JC20 Rec'd PCT/PTO 27 MAR 2002

FORM PTO-1390 (Modified) (REV 11-2000) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER
GRP-0013

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR
10/089540

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/DK00/00529	**27 September 2000**	**28 September 1999**

TITLE OF INVENTION
METHOD OF MEASURING BONE STRENGTH, APPARATUS FOR MEASURING BONE STRENGTH AND FIXATION DEVICE

APPLICANT(S) FOR DO/EO/US
KRISTIAN BUNDGARD

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include itens (5), (6), (9) and (24) indicated below.
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
   a. ☒ is attached hereto (required only if not communicated by the International Bureau).
   b. ☐ has been communicated by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☐ is attached hereto.
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
   a. ☐ are attached hereto (required only if not communicated by the International Bureau).
   b. ☐ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A copy of the International Search Report (PCT/ISA/210).

Items 13 to 20 below concern document(s) or information included:

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
20. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
22. ☒ Certificate of Mailing by Express Mail
23. ☐ Other items or information:

"Express Mail" mailing label number EL871056336US
Date of Deposit March 27, 2002
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Jennifer Matsen
(Typed or printed name of person mailing paper or fee)

(Signature of person mailing paper or fee)

PCTUS1/REV03

JC13 Rec'd PCT/PTO 27 MAR 2002

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
10/089540	PCT/DK00/00529	GRP-0013

24. The following fees are submitted:.

	CALCULATIONS	PTO USE ONLY
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :		
☐ Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO **$1040.00**		
☒ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO **$890.00**		
☐ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO **$740.00**		
☐ International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) **$710.00**		
☐ International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) **$100.00**		
ENTER APPROPRIATE BASIC FEE AMOUNT =	**$890.00**	
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).	**$0.00**	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	37 - 20 =	17	x $18.00	**$306.00**	
Independent claims	5 - 3 =	2	x $84.00	**$168.00**	
Multiple Dependent Claims **(check if applicable).**			☐	**$0.00**	

TOTAL OF ABOVE CALCULATIONS =	**$1,364.00**	
☒ Applicant claims small entity status. See 37 CFR 1.27). The fees indicated above are reduced by 1/2.	**$682.00**	
SUBTOTAL =	**$682.00**	
Processing fee of **$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (f)). +	**$0.00**	
TOTAL NATIONAL FEE =	**$682.00**	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) **(check if applicable).** ☐	**$0.00**	
TOTAL FEES ENCLOSED =	**$682.00**	
	Amount to be: refunded	$
	charged	$

a. ☒ A check in the amount of $682.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. ______________ in the amount of ______________ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 06-1130 A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Daniel F. Drexler
CANTOR COLBURN LLP
55 Griffin Road South
Bloomfield, CT 06002
Telephone: 860-286-2929
Customer No. 23413

SIGNATURE

Daniel F. Drexler
NAME

47,535
REGISTRATION NUMBER

3-27-02
DATE

Express Mail No. #EL871056336US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: KRISTIAN BUNDGARD

FOR: METHOD OF MEASURING BONE STRENGTH, APPARATUS FOR MEASURING BONE STRENGTH AND FIXATION DEVICE

PRELIMINARY AMENDMENT

"Express Mail" mailing label number EL871056336US
Date of Deposit March 27, 2002
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.
Jennifer Watson
(Typed or printed name of person mailing paper or fee)

(Signature of person mailing paper or fee)

The Assistant Commissioner
Of Patents and Trademarks
Washington, DC 20231

Dear Sir:

Prior to the Examiner acting in the above-referenced application, please preliminary amend the specification and claims as follows:

IN THE SPECIFICATION:

A substitute specification is submitted along with a marked-up copy thereof as attached hereto.

IN THE CLAIMS

Please replace claims 1-37 with the following rewritten versions:

1. (Amended) Method of measuring strength of a bone healed after a fracture or an osteotomy whereby external fastening means are attached onto the bone in at least two locations, whereby said external fastening means are provided with means for detection and/or measurement of relative displacement between said at least two external fastening means, whereby the bone is subjected to strain, and whereby corresponding

measurements and/or detections are made of the relative displacement by contactless measurement and/or detection means.

2. (Amended) Method according to claim 1, wherein the measurement and/or detection of the relative displacement comprises measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement.

3. (Amended) Method according to claim 1, wherein the external fastening means are part of external fixing means for supporting the bone.

4. (Amended) Method according to claim 1,wherein the bone is subjected to strain and wherein the strain is measured, detected and/or visualized.

5. (Amended) Method according to claim 1,wherein the corresponding measurements and/or detections of the relative displacement and the strain on the bone are correlated and/or recorded.

6. (Amended) Method of measuring the strength of a bone healed after a fracture or an osteotomy, whereby external fastening means are attached onto the bone in at least two locations, whereby said external fastening means are provided with means for detection and/or measurement of relative displacement between said at least two external fastening means, whereby the bone is subjected to strain, and whereby corresponding measurements and/or detections are made of the relative displacement in at least two dimensions and of the strain on the bone.

7. (Amended) Method according to claim 6, wherein the measurement and/or detection of the relative displacement comprise measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement.

8. (Amended) Method according to claim 6,wherein the external fastening means are part of external fixing means for supporting the bone.

9. (Amended) Method according to claim 6, wherein the bone is subject to strain by the patient and wherein the strain is measured, detected and/or visualized.

10. (Amended) Method according to claim 6, wherein the corresponding measurements and/or detections of the relative displacement and of the strain on the bone are correlated and/or recorded.

11. (Amended) Apparatus for measuring the strength of a bone having a healed osteotomy or a healed bone fracture, said apparatus comprising external fastening means for connection to the bone in at least two locations, said external fastening means being provided with means for detection and/or measurement of relative displacement by contactless measurement and/or detection means between said at least two external fastening means.

12. (Amended) Apparatus according to claim 11, wherein the apparatus is provided with means for measurement and/or detection of induced strain on the bone.

13. (Amended) Apparatus according to claim 11, wherein the apparatus is provided with means for correlating said measurements and/or detections of relative displacement of strain.

14. (Amended) Apparatus according to claim 11, wherein the means for contactless measurement and/or detection of relative displacement between said at least two external fastening means facilitate measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement.

15. (Amended) Apparatus according to claim 11, wherein the external fastening means are part of external fixing means for supporting the bone.

16. (Amended) Apparatus according to claim 11, wherein the apparatus is provided with means for supporting one or both ends of a limb, for positioning one end of a limb and/or for transferring forces to/from the limb to/from measuring means.

17. (Amended) Apparatus according to claim 11, wherein the apparatus comprises means for indicating, visualizing and/or recording the measured and/or detected strain.

18. (Amended) Apparatus according to claim 11, wherein the apparatus comprises means for indicating, visualizing and/or recording the measured and/or detected relative displacement.

19. (Amended) Apparatus for measuring the strength of a bone having a healed osteotomy or a healed bone fracture, said apparatus comprising external fastening means for connection to the bone in at least two locations, said external fastening means being provided with means for detection and/or measurement of relative displacement in at least two dimensions between said at least two external fastening means, said apparatus being provided with means for measurement and/or detection of induced strain on the bone.

20. (Amended) Apparatus according to claim 19, wherein the apparatus is provided with means for correlating said measurements and/or detections of relative displacement and strain.

21. (Amended) Apparatus according to claim 19, wherein the means for detection and/or measurement of relative displacement in at least two dimensions between said at least two external fastening means facilitate measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement.

22. (Amended) Apparatus according to claim 19, wherein the external fastening means are part of external fixing means for supporting the bone.

23. (Amended) Apparatus according to claim 19, wherein the apparatus is provided with means for supporting one or both ends of a limb, for positioning one end of a limb and/or for transferring forces to/from the limb to/from measuring means.

24. (Amended) Apparatus according to claim 19, wherein the apparatus comprises means for indicating, visualizing and/or recording the measured and/or detected strain.

25. (Amended) Apparatus according to claim 19 - 24, wherein the apparatus comprises means for indicating, visualizing and/or recording the measured and/or detected relative displacement.

26. (Amended) External fixator for supporting a bone of an animal or a human being, said fixator comprising means for fastening onto the bone in at least two locations and connecting means for providing a adjustable connection between said fastening means, wherein said connection means are replaceable and wherein measurement and/or detection means for detection and/or measurement of relative displacement between said at least two external fastening means are attachable onto said at least two external fastening means.

27. (Amended) External fixator according to claim 26, wherein said measurement and/or detection means for detection and/or measurement of relative displacement between said at least two external fastening means are contactless.

28. (Amended) External fixator according to claim 26, wherein said measurement and/or detection means for detection and/or measurement of relative displacement between said at least two external fastening means are configured for detection and/or measurement of relative displacement in at least two dimensions.

29. (Amended) External fixator according to claim 26, wherein said at least two external fastening means may each comprise or be connected to a structural member which surrounds the body part containing the bone at least partly, and in that said preferably adjustable connection between said fastening means may be connected to said structural members.

30. (Amended) External fixator according to claim 29, wherein said structural members comprise separate and/or relatively movable parts which are joinable and/or adjustable in order to surround a limb at least partly.

31. (Amended) External fixator according to claim 26, wherein the connection means comprise one, two, three, four or more connecting rods, which is adjustably placed between said at least two fastening means.

32. (Amended) External fixator according to claim 26, wherein the measurement and/or detection means for detection and/or measurement of relative displacement between said at least two external fastening means are attachable to said structural members forming part of or being connected to said at least two external fastening means.

33. (Amended) External fixator according to claim 26, wherein the measurement and/or detection means for detection and/or measurement of relative displacement are connected to the at least two external fastening means and/or said corresponding structural members by means which also serve as fixing means for said adjustable connection between said fastening means.

34. (Amended) External fixator according to claim 26, wherein the measurement and/or detection means for detection and/or measurement of relative displacement comprise electrical, magnetic or electromagnetic measurement and/or detection means.

35. (Amended) External fixator according to claim 34, wherein the measurement and/or detection means for detection and/or measurement of relative displacement comprises optical measurement and/or detection means.

36. (Amended) External fixator according to claim 26, wherein the contactless measurement and/or detection means for detection and/or measurement of relative displacement comprise one or more measurement and/or detection means.

37. (Amended) External fixator according to claim 36, wherein the measurement and/or detection means for detection and/or measurement of relative displacement in at least two dimensions comprise two or more measurement and/or detection means placed at a circumferential distance in relation to an axis of the bone.

<u>IN THE ABSTRACT</u>:

Please replace the abstract with the following rewritten version:

--ABSTRACT

Method and apparatus for measuring the strength of a bone, in particular a bone healed after a fracture or an osteotomy, whereby external fastening means are attached onto the bone in at least two locations. The external fastening means are provided with means for detection and/or measurement of relative displacement between the at least two external fastening means, the bone is subjected to strain, and corresponding measurements and/or detections are made of the relative displacement by contactless and/or two-dimensional measurement and/or detection means. Hereby, measurements are made which will provide a more accurate assessment of the strength and/or stiffness of a bone. The invention also relates to an external fixator facilitating a method and an apparatus according to the invention.--

REMARKS

Applicant requests entry of the above-identified amendments which conform the claims to U.S. practice. Further, a substitute specification is submitted along with a marked-up copy thereof pursuant to 37 CFR 1.125(b). Applicant requests that the substitute specification be entered in the present application and used for examination. No new matter is introduced by this Amendment or in the substitute specification as antecedent support is set forth in the original specification and claims.

Prosecution on the merits is respectfully requested.

If there are any charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130 maintained by Applicant's attorneys.

Respectfully submitted,
KRISTIAN BUNDGARD

CANTOR COLBURN LLP
Applicant's Attorneys

By:
Daniel F. Drexler
Registration No. 47,535
Customer No. 23413

Date: 3-27-02
Telephone: 860-286-2929

Version with Markings to Show Changes Made

IN THE CLAIMS:

1. (Amended/Marked up) Method of measuring ~~the~~ strength of a bone~~, in particular a bone~~ heal~~inged~~ed after a fracture or an osteotomy whereby external fastening means are attached onto the bone in at least two locations, whereby said external fastening means are provided with means for detection and/or measurement of relative displacement between said at least two external fastening means, whereby the bone is subjected to strain, and whereby corresponding measurements and/or detections are made of the relative displacement by contactless measurement and/or detection means.

2. (Amended/Marked up) Method according to claim 1, ~~characterized in that~~ wherein the measurement and/or detection of the relative displacement comprises measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement.

3. (Amended/Marked up) Method according to claim 1~~-or 2~~, ~~characterized in that~~ wherein the external fastening means are part of external fixing means for supporting the bone.

4. (Amended/Marked up) Method according to claim 1~~, 2 or 3, characterized in that~~ wherein the bone is subjected to strain~~, preferably by the patient,~~ and ~~in that~~wherein the strain is measured, detected and/or visualized.

5. (Amended/Marked up) Method according to ~~one or more of~~ claims 1~~, - 4, characterized in that~~ wherein the corresponding measurements and/or detections of the relative displacement and the strain on the bone are correlated and/or recorded.

6. (Amended/Marked up) Method of measuring the strength of a bone~~, in particular a bone~~ heal~~ing~~ed after a fracture or an osteotomy, whereby external fastening means are attached onto the bone in at least two locations, whereby said external fastening means are provided with means for detection and/or measurement of relative displacement between said at least two external fastening means, whereby the bone is subjected to strain, and whereby corresponding measurements and/or detections are made of the relative displacement in at least two dimensions and of the strain on the bone.

7. (Amended/Marked up) Method according to claim 6, ~~characterized in that~~ wherein the measurement and/or detection of the relative displacement ~~may~~ comprise measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement.

8. (Amended/Marked up) Method according to claim 6~~, or 7, characterized in that~~ wherein the external fastening means are part of external fixing means for supporting the bone.

9. (Amended/Marked up) Method according to claim 6, ~~7 or 8, characterized in that~~ wherein the bone is subject to strain by the patient and ~~in that~~wherein the strain is measured, detected and/or visualized.

10. (Amended/Marked up) Method according to ~~one or more of~~ claims 6~~–~~9, ~~characterized in that~~ wherein the corresponding measurements and/or detections of the relative displacement and of the strain on the bone are correlated and/or recorded.

11. (Amended/Marked up) Apparatus for measuring the strength of a bone~~, in particular a bone~~ having a heal~~ing~~ed osteotomy or a heal~~ing~~ed bone fracture, said apparatus comprising external fastening means for connection to the bone in at least two locations, said external fastening means being provided with means for detection and/or

measurement of relative displacement by contactless measurement and/or detection means between said at least two external fastening means.

12. (Amended/Marked up) Apparatus according to claim 11, ~~characterized in that~~ wherein the apparatus is provided with means for measurement and/or detection of induced strain on the bone.

13. (Amended/Marked up) Apparatus according to claim 11~~ or 12~~, ~~characterized in that~~ wherein the apparatus is provided with means for correlating said measurements and/or detections of relative displacement of strain.

14. (Amended/Marked up) Apparatus according to ~~one or more of~~ claims 11—~~13~~, ~~characterized in that~~ wherein the means for contactless measurement and/or detection of relative displacement between said at least two external fastening means facilitate measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement.

15. (Amended/Marked up) Apparatus according to ~~one or more of~~ claims 11—~~14~~, ~~characterized in that~~ wherein the external fastening means are part of external fixing means for supporting the bone.

16. (Amended/Marked up) Apparatus according to ~~one or more of~~ claims 11—~~15~~, ~~characterized in that~~ wherein the apparatus is provided with means for supporting one or both ends of a limb, for positioning one end of a limb and/or for transferring forces to/from the limb to/from measuring means.

17. (Amended/Marked up) Apparatus according to ~~one or more of~~ claims 11—~~16~~, ~~characterized in that~~ wherein the apparatus comprises means for indicating, visualizing and/or recording the measured and/or detected strain.

18. (Amended/Marked up) Apparatus according to ~~one or more of~~ claims 11—~~17~~, ~~characterized in that~~ wherein the apparatus comprises means for indicating, visualizing and/or recording the measured and/or detected relative displacement.

19. (Amended/Marked up) Apparatus for measuring the strength of a bone~~, in particular a bone~~ having a heal~~ing~~ed osteotomy or a heal~~ing~~ed bone fracture, said apparatus comprising external fastening means for connection to the bone in at least two locations, said external fastening means being provided with means for detection and/or measurement of relative displacement in at least two dimensions between said at least two external fastening means, said apparatus being provided with means for measurement and/or detection of induced strain on the bone.

20. (Amended/Marked up) Apparatus according to claim 19, ~~characterized in that~~ wherein the apparatus is provided with means for correlating said measurements and/or detections of relative displacement and strain.

21. (Amended/Marked up) Apparatus according to claim 19~~ or 20~~, ~~characterized in that~~ wherein the means for detection and/or measurement of relative displacement in at least two dimensions between said at least two external fastening means facilitate measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement.

22. (Amended/Marked up) Apparatus according to claim 19, ~~20 or 21,~~ ~~characterized in that~~ wherein the external fastening means are part of external fixing means for supporting the bone.

23. (Amended/Marked up) Apparatus according to ~~one or more of~~ claims 19—~~22~~, ~~characterized in that~~ wherein the apparatus is provided with means for supporting one or both ends of a limb, for positioning one end of a limb and/or for transferring forces to/from the limb to/from measuring means.

24. (Amended/Marked up) Apparatus according to ~~one or more of~~ claims 19~~—23~~, ~~characterized in that~~ wherein the apparatus comprises means for indicating, visualizing and/or recording the measured and/or detected strain.

25. (Amended/Marked up) Apparatus according to ~~one or more of~~ claims 19 - 24, ~~characterized in that~~ wherein the apparatus comprises means for indicating, visualizing and/or recording the measured and/or detected relative displacement.

26. (Amended/Marked up) External fixator for supporting a bone~~, e.g. a bone in a limb~~ of an animal or a human being, said fixator comprising means for fastening onto the bone in at least two locations and connecting means for providing a ~~preferably~~ adjustable connection between said fastening means, wherein said connection means are replaceable and wherein measurement and/or detection means for detection and/or measurement of relative displacement between said at least two external fastening means are attachable onto said at least two external fastening means.

27. (Amended/Marked up) External fixator according to claim 26, ~~characterized in that~~ wherein said measurement and/or detection means for detection and/or measurement of relative displacement between said at least two external fastening means are contactless.

28. (Amended/Marked up) External fixator according to claim 26~~— or 27~~, ~~characterized in that~~ wherein said measurement and/or detection means for detection and/or measurement of relative displacement between said at least two external fastening means are configured for detection and/or measurement of relative displacement in at least two dimensions.

29. (Amended/Marked up) External fixator according to ~~one or more of~~ claims 26~~—28~~, ~~characterized in that~~ wherein said at least two external fastening means may each comprise or be connected to a structural member which surrounds the body part

containing the bone at least partly, and in that said preferably adjustable connection between said fastening means may be connected to said structural members.

30. (Amended/Marked up) External fixator according to claim 29, ~~characterized in that~~ wherein said structural members ~~may~~ comprise separate and/or relatively movable parts which ~~may be~~are join~~ed~~able and/or adjust~~ed~~able in order to surround a limb at least partly.

31. (Amended/Marked up) External fixator according to ~~one or more of~~ claims 26—30, ~~characterized in that~~ wherein the connection means comprise one, two, three, four or more connecting rods, which ~~may preferably be~~is adjustably placed between said at least two fastening means.

32. (Amended/Marked up) External fixator according to ~~one or more of~~ claims 26—31, ~~characterized in that~~ wherein the measurement and/or detection means for detection and/or measurement of relative displacement between said at least two external fastening means are attachable to said structural members forming part of or being connected to said at least two external fastening means.

33. (Amended/Marked up) External fixator according to ~~one or more of~~ claims 26—32, ~~characterized in that~~ wherein the measurement and/or detection means for detection and/or measurement of relative displacement ~~may be~~are connected to the at least two external fastening means and/or said corresponding structural members by means which also serve as fixing means for said ~~preferably~~ adjustable connection between said fastening means.

34. (Amended/Marked up) External fixator according to ~~one or more of~~ claims 26—33, ~~characterized in that~~ wherein the measurement and/or detection means for detection and/or measurement of relative displacement ~~may~~ comprise electrical, magnetic or electromagnetic measurement and/or detection means.

35. (Amended/Marked up) External fixator according to claim 34, ~~characterized in that~~ wherein the measurement and/or detection means for detection and/or measurement of relative displacement comprises optical measurement and/or detection means.

36. (Amended/Marked up) External fixator according to ~~one or more of~~ claims 26~~—35~~, ~~characterized in that~~ wherein the contactless measurement and/or detection means for detection and/or measurement of relative displacement comprise one or more measurement and/or detection means.

37. (Amended/Marked up) External fixator according to claim 36, ~~characterized in that~~ wherein the measurement and/or detection means for detection and/or measurement of relative displacement in at least two dimensions comprise two or more measurement and/or detection means placed at a circumferential distance~~, e.g.~~ in relation to an axis of the bone.

IN THE ABSTRACT:

~~Abstract:~~ABSTRACT

Method and apparatus for measuring the strength of a bone, in particular a bone heal~~ing~~ed after a fracture or an osteotomy, whereby external fastening means are attached onto the bone in at least two locations. The external fastening means are provided with means for detection and/or measurement of relative displacement between ~~said~~the at least two external fastening means, the bone is subjected to strain, and corresponding measurements and/or detections are made of the relative displacement by contactless and/or two-dimensional measurement and/or detection means.

Hereby, measurements are made which will provide a more accurate assessment of the strength and/or stiffness of a bone. The invention also relates to an external fixator facilitating a method and an apparatus according to the invention.

~~(Fig. 3)~~

SUBSTITUTE SPECIFICATION (MARKED-UP VERSION)

METHOD OF MEASURING BONE STRENGTH, APPARATUS FOR MEASURING BONE STRENGTH AND FIXATION DEVICE

BACKGROUND OF THE INVENTION

Field of the invention

The invention relates to a method of measuring the strength or stiffness of a bone, an apparatus for measuring the strength or stiffness of a bone and an external fixator for supporting a bone.

~~**Background of the invention**~~Description of Related Art

When a bone, for example a bone in a limb of an animal or a human being, is healing after a fracture, it is known to support such a bone with an external holding device called a fixation device or a fixator. Such a fixator serves to fixate the ends of the bone in relation to each other as well as to carry the load or part of the load which a patient may have to place on the bone during the healing process.

Further, it is known to use such a fixator when extending the length of a bone. This is done by performing an osteotomy, i.e. by performing a substantially transversal cut in the bone, by preferably gradually pulling the ends of the bone apart at a predetermined and limited distance and by fixating the ends of the bone adjacently to each other. Hereby, the space between the ends of the bone will gradually be filled with new bone material, after which the ends of the bone may be pulled apart once again in order to increase the length of the bone even further. Eventually, when the bone has reached the required length and developed the necessary strength and stiffness, the external fixating device, the fixator, which may be unilateral, semicircular or circular, may be removed.

In order to determine the right time for removal of the fixator during a healing process and/or during a revalidation process, it is known to evaluate the consolidation of the fracture or the osteotomy by using radiography, e.g. x-ray-technology, DEXA (dual or double energy x-ray absorption), CT-scanning, or other similar methods such as ultrasound, other scanning methods etc. However, these methods rely on the assessment skills and experience of the person or persons, e.g. the physician or the surgeon, using the method. Thus, an accurate and objective determination can not be made by using this method. Further, it is known to perform a purely physical examination in order to determine the strength or stiffness of a healing bone, e.g. by having the physician grab the limb and physically try to flex, bend and/or twist the limb in order to assess the state of healing. Of course, this is based solely on the assessment skills and experience of the person or persons, e.g. the physician, carrying out the examination.

In this context, it is understood that the terms stiffness and strength of a bone will refer to the same physical parameter of a bone, e.g. the resistance to deformation once a force or load is placed on the bone.

Further, it is known to detect or measure the deformation of a part using a fixator, when a load is placed on the assembly of the bone and the fixator.

An example of this is described in US 5,792,076, which relates to a fixation device having an elongated optical fiber. The fixation device is affixed to a patient's bone by pins attached to a fixation bar. The fixation bar comprises the elongated optical fiber and light is transmitted through the optical fiber to an exit point where the intensity is measured. As the bone fracture is gradually healing, the load, e.g. the weight or part of the weight of the patient, will gradually be transferred from the fixation bar to the bone of the patient, giving rise to a change in the intensity of the transmitted light. Thus, a physician will be able to assess when the fracture has fully healed by observing the change in the light intensity.

This method, however, suffers from the disadvantage that the fixation bar is an integral part of the system of which the strength is evaluated. Thus, the result of the assessments will not necessarily provide a true picture of the strength of the bone. Further, the assessment is given of a deformation of the fixation bar which is mounted unilaterally. Thus, the deformation of the bone in other dimensions will not be evaluated by this method. Further, in many cases, a fractured bone will have one or more neighboring bones, for example in a lower arm or in a lower leg, which means that when a limb is subjected to a certain load or a strain, this load or strain will be dissipated on the bones in the limb and possibly also on any fixation devices used. Thus, the load, force or strain placed on the fractured bone will be difficult to determine on the basis of the load placed on the limb, and the deformation of the bone and the limb will depend on the assembly as a whole. Thus, for example, a load on a limb in an axial direction may of course result in an axial deformation of the fracture bone, but it may also result in an angular deformation, e.g. a twisting motion, and a bending deformation.

It is also known to use means for measuring or detecting the strain and/or deformation of the bone, wherein ~~said~~the means is attached to the bone or the limb.

An example of such a method is described in EP 0 324 279 A1, wherein the bending of e.g. a lower leg having a healing fracture is measured by means of a goniometer. Bone pins are placed on each side of the fracture site, and a goniometer is attached to these pins and positioned substantially parallelly with the axis of the bone. The deformation, i.e. the bending of the bone, is measured while simultaneously applying force to the bone of the patient. This force, which may be constituted by the weight of the limb, e.g. the lower leg, may be measured by a scale placed under one end of the limb, e.g. under the heel of the patient.

Another example of such a system is described in US 5,339,533.

Both systems also suffer from the disadvantages described above with the exception of the fixation bar which is not applied in these systems when determining the

strength of the bone. However, by using these systems, only the bending deformation of the bone will be determined. Thus, the true strength of the bone will not be evaluated.

A further prior art fixation device is described in WO 98/00062. This fixation device has two ring-shaped members attached to a fractured bone by pins on each side of the fracture. The two ring-shaped members are connected to each other by connecting studs in order to support the bone. One of the ring members comprises a first and a second element which may be rotated in relation to each other. The first element carries the connecting studs while the second element is connected to the pins. The two elements may be rotated in relation to each other when a force is exerted on the bone, i.e. the healing fracture, via one of the elements whereby the two bone parts will be subject to a torque attempting to twist the two bone parts in relation to each other. The extent of the movement, e.g. the angle, and the exerted force corresponding to the torque, may be measured in order to obtain values reflecting the strength of the bone.

By this system, only the torsional strength of the bone, e.g. the healing bone, may be determined which may not provide a true picture of the strength of the healing bone, e.g. the state of healing, as the resistance to axial deformation and bending deformation will not be detected and these resistances may not be proportional to the resistance of a torsional force. Thus, the true state of the healing process and the true strength of the bone, e.g. the healing bone fracture, may not be determined by this method.

The prior art methods and systems for determining the strength or stiffness of a healing bone generally suffer from the drawback that the strength of the healing bone will not be determined with the required accuracy. Thus, the optimal time for removal of a fixation device cannot be determined by using these methods and systems.

When trying to decide when a healing bone, e.g. a bone healing after a fracture or after an ostetomy performed in order to increase, reduce or alter the angling of the bone, has gained sufficient strength to allow a fixation device, e.g. an external fixation device to be loosened or removed, it is important to find the optimal or nearly optimal time for loosening or removal.

If the fixation device is removed too soon, the healing bone may be refractured, whereby the patient will suffer additional discomfort and possibly complications in the healing process. Hereby, the healing period will be extended and the health service as well as society in general will have to spend unnecessary resources, e.g. loss of work, occupation of hospital resources etc., and the patient will suffer from additional discomfort and loss of income.

Therefore, there has been a tendency to extend the period of which a fixation device is used until it is safe to assume that a refracture will not occur. This tendency is enhanced by the fact that existing methods of determining the state of a healing bone involve some inaccuracies. Consequently, in most cases, the fixation device is left on the patient for a longer period of time than is necessary in order to ensure that a refracture will not occur.

As the healing process has proven to be accelerated when the fracture is subjected to normal or near-normal load situations as soon as it is deemed safe, the healing process as a whole is reduced. However, as there is a tendency to maintain the healing bone supported by the fixator longer than strictly necessary in order to be on the safe side, this will extend the healing and revalidation time leading to unnecessary resource spending, loss of work, unnecessary occupation of hospital and medical resources, loss of income, prolonged discomfort of the patient etc.

Thus, it is an object of the invention to provide an improved method of determining the strength or stiffness of a bone, and in particular a healing bone. A further object of the invention is to provide a method of determining the strength of a bone, and in particular a healing bone, whereby the strength of the bone may be determined with

improved accuracy, whereby an improved method of determining the time for removal of a holding device, and in particular an external holding device, may be provided.

Another object of the invention is to provide an improved apparatus for determining the strength or stiffness of a bone, and in particular a healing bone. A still further object of the invention is to provide an apparatus for determining the strength or stiffness of a bone, and in particular a healing bone, whereby the strength or stiffness of the bone may be determined with improved accuracy, whereby an improved method of determining the time for removal of a holding device, and in particular an external holding device, may be provided.

It is also an object of the invention to provide a fixation device for a healing bone, whereby the fixation device will facilitate improved determination of the strength or stiffness of the bone, e.g. the healing bone.

It is a further object of the invention to provide means for reducing the time during which a patient will have to be equipped with an external fixator, whereby costs involved with healing bones, e.g. bones healing after a fracture or after an osteotomy, will be reduced.

These and other objects are achieved by the invention.

~~**Summary of the invention**~~BRIEF SUMMARY OF THE INVENTION

~~As stated in claim 1, t~~The invention relates to a method of measuring the strength of a bone, in particular a bone healing after a fracture or an osteotomy which has been performed in order to extend, reduce or alter the angle of the bone, whereby external fastening means are attached onto the bone in at least two locations, whereby ~~said~~the external fastening means are provided with means for detection and/or measurement of relative displacement between ~~said~~the at least two external fastening means, whereby the bone is subject to strain, and whereby corresponding measurements

and/or detections are made of the relative displacement by contactless measurement of and/or detection means.

Hereby, a measurement is made which will provide a more accurate assessment of the strength and/or stiffness of a bone as the measuring arrangements will not have any influence on the result of the measurements, e.g. the measuring arrangements will not contribute to the stiffness of the structure, i.e. the bone or bones subject to the measurements. Further, the contactless measuring arrangement will allow increased flexibility when setting up the arrangement and also allow measurements to be performed in more than one dimension.

~~Preferably, as stated in claim 2, m~~Measurement and/or detection of the relative displacement may comprise measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement. Hereby, measurements may be made of any deformations induced by any given force or load placed on the bone.

~~As stated in claim 3, t~~The external fastening means may be part of external fixing means for supporting the bone. Hereby, a flexible and convenient way of obtaining measurements is achieved which are necessary for evaluating the healing state of a bone as fastening means already attached onto the patient may be used when performing the method.

~~As stated in claim 4, t~~The bone is subjected to strain, preferably by the patient, and the strain is measured, detected and/or visualized. Hereby, deformations may be induced in a convenient manner and the cause of the deformations be documented.

~~As stated in claim 5, t~~The corresponding measurements and/or detections of the relative displacement and strain on the bone may be correlated and/or recorded, whereby a comparison of the deformations and the causes may be made, whereby an assessment of the strength of the bone may be conveniently performed.

The invention also concerns a method~~, as stated in claim 6,~~ which relates to the measurement of the strength of a bone, in particular a bone healing after a fracture or after an osteotomy, whereby external fastening means are attached onto the bone in at least two locations, whereby ~~said~~the external fastening means are provided with means for detection and/or measurement of relative displacement between ~~said~~the at least two external fastening means, whereby the bone is subjected to strain, and whereby corresponding measurements and/or detections are made of the relative displacement in at least two dimensions of the strain on the bone.

Hereby, a method is achieved which will provide a more accurate assessment of the strength and/or stiffness of a bone as the measuring arrangements will allow measurements to be performed in more than one dimension providing improved measurements of the induced deformations that those of prior art methods.

~~Preferably, as stated in claim 7, t~~The measurement and/or detection of the relative displacement may comprise measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement. Hereby, measurements may be made of any deformations induced by any given force or load placed on the bone.

~~As stated in claim 8, t~~The external fastening means may be part of external fixing means for supporting the bone. Hereby, a flexible and convenient way of obtaining the measurements necessary for evaluating the healing state of a bone is achieved as fastening means already attached onto the patient may be used when applying the method.

~~As stated in claim 9, t~~The bone may be subjected to strain by the patient and the strain may be measured, detected and/or visualized. Hereby, deformations may be induced in a convenient manner and the cause of the deformations be documented.

~~As stated in claim 10, t~~The corresponding measurements and/or detections of the relative displacement and the strain on the bone may be correlated and/or recorded,

whereby a comparison of the deformations and the causes may be made, whereby an assessment of the strength of the bone may be conveniently performed.

Further, the invention relates to an apparatus~~, as claimed in claim 11,~~ for measurement of the strength of a bone, in particular a bone having a healing osteotomy or a healing bone fracture, the~~said~~ apparatus comprising external fastening means for connection to the bone in at least two locations, the~~said~~ external fastening means being provided with means for detection and/or measurement of relative displacement by contactless measurement and/or detection means between the~~said~~ at least two external fastening means.

Hereby, an apparatus is provided whereby a measurement is made which will provide a more accurate assessment of the strength and/or stiffness of a bone as the measuring arrangements will not have any influence on the result of the measurements, e.g. the measuring arrangements will not contribute to the stiffness of the structure, i.e. the bone or bones subject to the measurements. Further, the contactless measuring arrangement will allow increased flexibility when setting up the arrangement and allow measurements to be performed in more than one dimension by the apparatus.

~~Preferably, as stated in claim 12, t~~The apparatus is provided with means for measurement -and/or detection of induced strain on the bone. Hereby, the cause of the deformations may be readily documented and utilized in connection with the assessment of the bone strength.

~~As stated in claim 13, t~~The apparatus may be provided with means for correlating the~~said~~ measurements and/or detections of relative displacement and strain, whereby a comparison of the deformations and the causes may be made by the apparatus, whereby an assessment of the strength of the bone may be conveniently performed on the basis hereof.

~~As stated in claim 14, t~~The means for contactless measurement and/or detection of relative displacement between the~~said~~ at least two external fastening means may facilitate measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement. Hereby, measurements may be made of any deformations induced by any given force or load placed on the bone.

~~As stated in claim 15, t~~The external fastening means may be part of external fixing means for supporting the bone. Hereby, an apparatus according to this embodiment may be utilized in a flexible and convenient way to obtain the measurements necessary for assessing the healing state of a bone as fastening means already attached onto the patient may be used in connection with or as part of the apparatus.

~~As stated in claim 16, t~~The apparatus is provided with means for supporting one or both ends of a limb, for positioning one end of a limb and/or for transferring force to/from the limb to/from measuring means. Hereby, the patient may exert the load or force necessary to induce the deformations of the bone or bones. The weight of a limb alone may constitute a load or the patient may place more or less bodyweight on the limb. When one end of the limb is positioned, preferably by a bracket or similar means, the patient may exert force on the bone in any other direction than the vertical direction, e.g. horizontal direction, attempting to twist the bone etc., whereby more varied deformations may be induced.

~~As stated in claim 17, t~~The apparatus may comprise means for indicating, visualizing and/or recording the measured and/or detected strain. Hereby, the cause of the deformations may be documented by the apparatus, whereby an assessment of the strength of the bone may be performed by a skilled user.

~~As stated in claim 18, t~~The apparatus may preferably comprise means for indicating, visualizing and/or recording the measured and/or detected relative displacement, whereby the result of the measurements may be used for immediate or subsequent assessments.

The invention further relates to an apparatus~~, as claimed in claim 19,~~ for measurement of the strength of a bone, in particular a bone having a healing osteotomy or a healing bone fracture, the~~said~~ apparatus comprising external fastening means for connection to the bone in at least two locations, the~~said~~ external fastening means being provided with means for detection and/or measurement of relative displacement in at least two dimensions between the~~said~~ at least two external fastening means, and the~~said~~ apparatus being provided with means for measurement and/or detection of an induced strain on the bone.

Hereby, an apparatus is provided by means of which a more accurate assessment of the strength and/or stiffness of a bone may be performed as the measuring arrangements of the apparatus will facilitate measurements in more than one dimension and thus provide improved measurements of the induced deformations than those of prior art apparatuses.

~~Preferably, as stated in claim 20, t~~The apparatus may be provided with means for correlating the~~said~~ measurements and/or detections of relative displacement and strain, whereby a comparison of the deformations and the causes may be provided by the apparatus, whereby an assessment of the strength of the bone may be conveniently performed by a skilled person, e.g. a physician.

~~Preferably, as stated in claim 21, t~~The means for detection and/or measurement of relative displacement in at least two dimensions between the~~said~~ at least two external fastening means may facilitate measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement. Hereby, measurements may be made of any deformations induced by any given force or load placed on the bone. The means for detection and/or measurement of relative displacement in at least two dimensions may be configured as mechanical measuring means, e.g. slide gauges or other similar means connected to the two external fastening means in such a manner that measurements may be made in two or more dimensions.

~~A stated in claim 22, t~~The external fastening means may be part of external fixing means for supporting the bone. Hereby, an apparatus according to this embodiment may be utilized in a flexible and convenient way to obtain the measurements necessary for assessing the healing state of a bone as fastening means already attached onto the patient may be used in connection with or as part of the apparatus.

~~As stated in claim 23, t~~The apparatus may be provided with means for supporting one or both ends of a limb, for positioning one end of a limb and/or for transferring force to/from the limb to/from measuring means. Hereby, the patient may exert the load or force necessary to induce the deformations of the bone or bones. The weight of a limb may constitute a load alone or the patient may place more or less bodyweight on the limb. When one end of the limb is positioned, preferably by a bracket or similar means, the patient may exert a force on the bone in any other direction than the vertical direction, e.g. horizontal direction, attempting to twist the bone etc., whereby more varied deformations may be induced.

~~As stated in claim 24, t~~The apparatus may comprise means for indicating, visualizing and/or recording the measured and/or detected strain. Hereby, the cause of the deformations may be documented by the apparatus, whereby an assessment of the strength of the bone may be performed by a skilled user.

~~As stated in claim 25, t~~The apparatus may comprise means for indicating, visualizing and/or recording the measured and/or detected relative displacement, whereby the result of the measurements may be used for immediate or subsequent assessments.

Finally, the invention also pertains to an external fixation device~~, as stated in claim 26,~~ which relates to an external fixator for supporting a bone, e.g. a bone in a limb of an animal or a human being, the~~said~~ fixator comprising means for fastening onto the bone in at least two locations and connecting means for providing a preferably adjustable connection between the~~said~~ fastening means, wherein the~~said~~ connection means are replaceable and wherein measurement and/or detection means for detec-

tion and/or measurement of relative displacement between the~~said~~ at least two external fastening means are attachable to the~~said~~ at least two external fastening means.

Hereby, a fixator for supporting a bone or bones is provided which may also serve as fastening means when performing measurements of the flexibility of the bone. Thus, the measurements and hence the assessment of the healing state of the bone may be performed in a expedient manner when a fixator according to the invention is utilized.

~~Preferably, as stated in claim 27, said~~The measurement and/or detection means for detection and/or measurement of relative displacement between the~~said~~ at least two external fastening means are contactless. Hereby, a measurement may be made which will provide a more accurate assessment of the strength and/or stiffness of a bone, as the measuring arrangements will not have any influence on the result of the measurements, e.g. the measuring arrangements will not contribute to the stiffness of the structure, i.e. the bone or bones subject to the measurements. Further, the contactless measuring arrangement will allow increased flexibility when setting up the arrangement and also allow measurements to be performed in more than one dimension.

~~As stated in claim 28, said~~The measurement and/or detection means for detection and/or measurement of relative displacement between the~~said~~ at least two external fastening means may be configured for detection and/or measurement of relative displacement in at least two dimensions. Hereby, a more accurate assessment of the strength and/or stiffness of a bone may be performed as the measuring arrangements will allow measurements to be performed in more than one dimension and provide better measurements of the induced deformations than those of prior art systems. The means for detection and/or measurement of relative displacement in at least two dimensions may be configured as mechanical measuring means, e.g. slide gauges or other similar means connected to the two external fastening means in such a manner that measurements may be made in two or more dimensions. Other measuring means than purely mechanical ones may be used as well.

~~As stated in claim 29, said~~The at least two external fastening means may each comprise or be connected to a structural member which surrounds the body part containing the bone at least partly, the~~said~~ preferably adjustable connection between the~~said~~ fastening means being connected to the~~said~~ structural members. Hereby, the fastening means may constitute a firm connection for attachment of the measurement and/or detection means.

~~As stated in claim 30, said~~The structural members may comprise separate and/or relatively movable parts which may be joined and/or adjusted in order to surround a limb at least partly. Hereby, the structural members may be used flexibly as they may be adjusted in relation to the actual use as the structural members may be easily attached and removed.

~~As stated in claim 31, t~~The connection means comprises one, two, three, four or more connecting rods which may preferably be adjustably placed between the~~said~~ at least two fastening means. Hereby, a versatile fixator is achieved which may be used in a wide number of applications.

~~As stated in claim 32, t~~The measurement and/or detection means for detection and/or measurement of relative displacement between the~~said~~ at least two external fastening means are attachable to the~~said~~ structural members forming part of or being connected to the~~said~~ at least two external fastening means. Hereby, the fastening means may conveniently be fastened onto appropriate places, e.g. the front of the bone, the side etc., and provide a firm connection.

~~As stated in claim 33, t~~The measurement and/or detection means for detection and/or measurement of relative displacement may be connected to the at least two external fastening means and/or the~~said~~ corresponding structural members by means which also serve as fixation means for the~~said~~ preferably adjustable connection between the~~said~~ fastening means. Hereby, the fastening of the measurement and/or detection

means may be performed in a surprisingly simple manner and by means of a minimum of technical means.

~~As stated in claim 34, t~~The measurement and/or detection means for detection and/or measurement of relative displacement may comprise electrical, magnetic or electromagnetic measurement and/or detection means. Hereby, the fixator may be flexibly used in connection with a number of different measuring arrangements selected according to actual use, actual measurement, and/or processing arrangements and/or other preferences.

~~As stated in claim 35, t~~The measurement and/or detection means for detection and/or measurement of relative displacement may comprise optical measurement and/or detection means, for example in the form of digital video cameras or light emitting devices such as for example LEDs. Hereby, an advantageous measuring arrangement is achieved which is relatively easy to install and use and which facilitates effortless use also by person without any particular technical skills.

~~As stated in claim 36, t~~The measurement and/or detection means for detection and/or measurement of relative displacement may comprise one or more measurement and/or detection means.

~~As stated in claim 37, t~~The measurement and/or detection means for detection and/or measurement of relative displacement in at least two dimensions comprise two or more measurement and/or detection means placed at a circumferential distance, e.g. in relation to an axis of the bone, whereby the accuracy of the measurements may be enhanced and hence also the accuracy of the assessment of the strength of the bone and consequently the healing state of the bone.

~~**The figures**~~BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be described below with reference to the drawings of which

~~f~~Fig. 1 illustrates a bone separated in two parts and deformations of this bone schematically,

~~f~~Fig. 2 shows a fixation device attached onto the lower leg of a human being,

~~f~~Fig. 3 illustrates the fixation device shown in ~~f~~Fig. 3 with deformation measuring means attached,

~~f~~Fig. 4 shows an alternative deformation measuring arrangement, and

~~f~~Fig. 5 shows a block diagram illustrating the signal processing according to a further embodiment of the invention.

~~Detailed description~~DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 illustrates a bone 10, for example a bone of a human being. This bone 10 has been separated in two parts 10a and 10b, for example a proximal part 10a and a distal part 10b. The separation may be due to a fracture or to an osteotomy operation. During healing, the bone will flex at the place of separation when exposed to stress. The flexing may be illustrated by the two bone part vectors 11a and 11b, extending from an origin 12a and 12b, respectively. The direction of these vectors represents axes of the bone parts 10a and 10b, e.g. local bone axes and not necessarily an axis of the bone 10.

Obviously, the bone parts 10a and 10b will move longitudinally when exposed to stress. For example, the bone parts will move towards each other when subjected to an at least partly longitudinal force, whereby the healing part of the bone will be compressed. This will be indicated by a reduction of the distance 13 between the origins 12a and 12b of the bone part vectors 11a and 11b, respectively.

Further, application of force and/or momentum to the bone 10 may induce a relative rotational movement of the two bone parts 10a and 10b, which is illustrated by a vector 14a and a vector 14b, extending from the origins 11a and 11b, respectively. These vectors 14a and 14b may extend at right angles from the bone part vectors 11a and 11b, respectively, and/or they may extend in one and the same direction, preferably in a direction perpendicular to one or both of the bone part vectors 11a and 11b.

In an unstrained situation, these vectors extend in a reference direction, illustrated by the punctuated lines 15a and 15b, respectively. As one or both of the bone parts may be rotated when strained, angles 16a and 16b between the vector 14a and the reference direction 15a and between the vector 14b and the reference direction 15b respectively, serve to indicate the rotational movement of the bone parts 10a and 10b and hence also the relative rotational displacement of the bone parts.

Finally, application of force and/or momentum to the bone 10 may induce an angular displacement of the bone parts 10a and 10b and hence the bone part vectors 11a and 11b, causing a change of direction of the bone part vectors. These angles may be indicated by the angle of the bone part vectors in relation to a reference direction, or by the angle of the vectors 14a and 14b, respectively, in relation to a reference direction (not shown) in a plane defined by the bone part vector 11a and the vector 14a and/or the bone part vector 11b and the vector 14b. As will be explained later, the latter of these two methods will be preferable in connection with the invention.

When determining the strength or stiffness of a bone, and in particular a healing bone, it is desirable to be able to determine all the above-defined relative movements, e.g. the change in distance 13, the change in difference between the angles 16a and 16b and the relative change of direction of the bone part vectors 11a and 11b when forces and/or torques may be exerted on a bone, an assembly of bones and/or a limb.

The invention will now be explained further by reference to an external holder or fixator as illustrated in fFig. 2. This holder may be used to support a fractured bone while healing or, as illustrated, for a leg 20 on which an osteotomy is performed in order to extend, reduce or alter the angle of the bone, and to support the bones during the healing process. The external fixator may be unilateral, e.g. support by only one axial supporting bar or rod, semicircular, e.g. support of half a circle surrounding the bone, or circular, e.g. support is essentially circumferentially.

In fFig. 2, the use of the external fixator is illustrated in connection with the lower leg of a human being, but the fixator may obviously also be used in connection with other limbs and/or bones if appropriately modified. Further, an external fixator may be used in connection with animals as well as human beings.

The fixator comprises a number of ring-shaped structural members 21, 22, 26 and 27. The upper ring-shaped member is attached onto one or both bones, the tibia 29 and the fibula 28, of the lower leg by bone pins, bone screws, bone rods or as shown by bone wires 23 connected to the ring-shaped member 21 by connectors 24 and 25. The connectors 24 and 25 allow the bone wire to be fastened onto the ring-shaped member 23 with sufficient tensile strength to assure a rigid connection between the ring-shaped member 21 and the bone or bones 29 and 28.

The ring-shaped member 22 is similarly connected to one or both of the bones 28 and 29 by wires 23 and connectors 24 and 25. The lower ring-shaped members 26 and 27 are fastened onto the lower part of one or both of the bones 29 and 28 in the same fashion.

The upper ring-shaped members 21 and 22 are located above the healing sites 29a and 28a of the tibia 29 and the fibula 28, respectively, and the lower ring-shaped members are located below the healing sites 29a and 28a. Connecting means 30 in the form of connecting rods are placed between the ring-shaped members in order to support the bones, i.e. the leg. The connecting rods are threaded, at least at the ends, whereby they can be connected to the ring-shaped members by nuts. Longer connecting rods 30a are located between the ring-shaped members 22 and 27 and shorter connecting rods 30b are located between the ring-shaped members 21 and 22 and the ring-shaped members 26 and 27.

As the connecting rods are threaded, the distance between the ring-shaped members can be adjusted. The distance between the ring-shaped members 21 and 22 and the ring-shaped members 26 and 27, respectively, can be adjusted in dependency of the actual placing of the corresponding bone wires 23. The distance between ring-shaped

members 22 and 27 can be adjusted by the connecting rods 30a in order to fixate the bone parts appropriately in relation to each other.

When the fixator is used in connection with a leg with a (simple) fracture, the fixator can be adjusted to achieve the natural relations between the bone parts, after which the relationship is maintained until the fracture site has healed sufficiently.

When the fixator is used in connection with a more complex fracture or in connection with a bone extension/reduction/re-angling, the connecting rods 30a are initially adjusted to define an appropriate distance between the bone ends, i.e. the fractured bone ends or the separated bone ends, whereby a healing process, e.g. a bone mass producing process, will begin. Once the healing has started, i.e. the production of bone mass, and has reached a certain stage, the connecting rods 30a can be adjusted to pull the bone ends further apart, whereby the healing process will proceed and produce bone mass in the now intermediate space between the bone parts. This may be repeated until the desired length of the bone or bones has been achieved. A consolidation of the healing site will then have to take place, after which the fixator may be loosened and/or eventually permanently removed.

The stage of the healing process, e.g. the stiffness or strength of the healing fracture site, can be determined as shown in ~~f~~Fig. 3. This figure corresponds to ~~f~~Fig. 2. However, the connecting rods 30a of the fixating device have been loosened (in the early stages of the healing process) or removed, leaving the leg and the bones 29 and 28 unsupported or partially unsupported. A number of light emitting devices such as for example light emitting diodes (LEDs) 31 has been placed on one of the upper ring-shaped members 22. These LEDs are each mounted at one end of a fixture 32, which has attachment means 33 at the other end by which it is connected to the ring-shaped member 22, for example by through-holes in the ring-shaped member.

Correspondingly, a bracket has been mounted on one of the lower ring-shaped members 27. The bracket comprises a number of rods 35 which are attached by clamping means 37 to the ring-shaped member 27 at the lower ends, for example by bolt and

nut. At the upper end of the rods 35, a ring-shaped support has been mounted, and a number of mini-cameras 34 have been placed on the support 35 and/or the rods 35. The cameras, which may be digital video cameras such as USB-cameras, are placed in such a manner that they are located in the proximity of the light emitting devices 31.

When a load, a force and/or a torque is exerted upon the leg 20, the bones will be able to flex freely, as the connecting rods have been removed. This flexing will be transferred to corresponding movements of the ring-shaped members 21 and 27 and hence also the light emitting devices 31 and the cameras 34. By reference to fFig. 1 and the corresponding explanation, it is evident that the relative movements of the light emitting devices 31 and the cameras 34 will provide a full and complete picture of the flexing of the bones in all possible dimensions, and when correlated with the load or force placed onto the bone or bones also on the strength of the healing structure, as will be explained at a later point.

For example, an axial deformation will be determined by a vertical change of the position of the image of the light-emitting device 31 on the corresponding camera 34. A rotational flexing will be determined by a horizontal change of the position of the image of the light-emitting device 31 on the corresponding camera 34, and as more than one LED/camera arrangement is used, in the example four, a bend, e.g. an angular flexing of the bone, will be detected by a difference in the changes of the positions of the image of the light-emitting device 31 on the corresponding camera 34. It is evident that more than two camera/LED-arrangements of this particular configuration placed at different locations may be necessary to achieve this. However, only one camera/light emitting arrangement will suffice to provide a measurement of the deformations in two or more dimensions as will be described at a later point. Processing of the signals or results from the cameras 34 is necessary in order to obtain results indicating the actual one, two or three-dimensional flexing movements/deformations. Such processing methods are known to persons skilled in the art and will not be described in detail.

Figure 3 shows that four camera/LED-arrangements may be used and evenly distributed on the circular ring-shaped support 36, e.g. with an angle interval of 90°. Other configurations obvious to a skilled person may be used as well, and additional camera/LED-arrangements may be used, e.g. two, three, four, five etc.

Further, it is obvious that the LED-arrangements 32, 33, 34 and the camera arrangements 34, 35, 36, 37 may be configured as units which may be attached onto the corresponding ring-shaped members 22 and 27 as units whereby the placing of the measuring arrangements may be performed in an easy and fast manner.

Fig. 3 illustrates the foot of the patient being placed on a force plate 38 in order to determine the load or force, which is exerted on the leg/bone/bones. This force plate 38 may be constituted by a simple weight, a weight cell or other suitable means. Further arrangements may be configured to measure or determine other forces than substantially vertical forces, e.g. horizontal forces, or torques exerted on the leg. These arrangements may comprise a bracket or similar means (not illustrated) connected to measurement and/or detection means. For example, these means may be arranged to transfer forces exerted by the patient to the weight cell or other measuring means arranged to measure the vertical forces, whereby these means may also be used to measure or indicate non-vertical loads or forces. Hereby, the patient may be able to exert a twisting torque on the leg, e.g. by attempting to turn his foot. The force in e.g. horizontal direction exerted by the foot may then be measured or detected by the measuring means related to the bracket. Further, the patient may exert bending force on the leg by attempting to push the foot forward, backwards or sideways, whereby the force may be measured or detected by the measuring arrangements in a similar manner.

The force exerted by a patient attempting to turn or twist his foot may also be determined by using for example a electromotor, e.g. an electrodynamic motor, arranged axially beneath the support. When the patient attempts to turn his foot, this will have to be done against a torque exerted by the motor. The torque can be determined, as will be obvious to a skilled person, by knowledge of the motor characteristics and by

determining the motor current. Further, the maximum torque may be controlled by controlling the motor current, whereby it can be avoided that the patient may place an excessively large load on the bone, as the motor will just allow further turning when the maximum torque has been reached.

Other safety means may be provided, e.g. audible or visible alarm means which will indicate to the patient and/or to the physician that a certain level of force has been reached which may harm the healing bone. The maximum level or levels of force may be selected and/or adjusted by the physician on the basis of the knowledge of the patient, the state of healing, former tests etc., whereby refractures and other harm to the patient and the healing bone/bones may be avoided. The audible or visible alarm means may also serve to indicate the actual level of force, for example by a frequency increase once the level of force exerted by the patient increases.

Other measuring means obvious to a person skilled in the art may also be utilized.

Another arrangement for measuring the relative flexing movements, e.g. the deformation of a bone, is illustrated in ~~fig~~Fig. 4. In this figure, only two ring-shaped structural members 22 and 27 of the fixating device are, of course, fixed onto a bone as described in connection with ~~f~~Figs. 2 and 3 are described. On one on these ring-shaped members 22 in the example, a camera 41 is placed and points towards the other ring-shaped member 27 in the example. On this ring-shaped member 27, a reference device 42, which must be placed in such a manner that it will be in the vision field of the camera 41 in an unstrained situation of the bone, is placed in a similar manner.

The reference device 42 comprises a number of indicator elements in the form of light emitting diodes (LEDs) 43 for positioning the reference device 42 in the right position in relation to the camera 41. These LEDs 43 are placed in a particular pattern, e.g. in parallel rows and columns as illustrated, in order to facilitate the adjustment and positioning of the reference device 42 and/or the camera 41.

Further, the reference device 42 comprises a number of indicator elements in the form of light emitting diodes (LEDs) 44 for detecting the relative movements, i.e. deformations of the bone. These LEDs 44 are placed opposite a mirror 45 which is placed at an angle of for example 45° in relation to the plane at which the LEDs 44 are positioned. By this arrangement, deformations of the bone in one, two or three dimensions can be detected and measured. For example, axial deformation can be detected as the distance between the LEDs 44 is known, whereby relative axial movements may be determined by processing the corresponding video images, e.g. the distances on the images. Further, rotational movements can be detected and measured as the initial positions of the reference device 42 and the LEDs 44 are known in the unrestrained situation. The angular movements can be detected and measured as the mirror 45 is involved, whereby the distance on the image between the rows and/or columns of LEDs 44 will change, i.e. the image of the distance between two rows will be larger in one end than in the other end and vice versa, when a tilt between the two ring-shaped members 22 and 27 is involved. Evidently, processing of the measurements from the camera 41 has to be performed in order to achieve values for the deformations of the bone/bones. Such processing may be performed in a number of ways which will be known to person skilled in the art.

Fig. 4 shows only one set of cameras with a reference device by which it will be possible to determine the deformations of a bone. More than one set of cameras and a reference device may be utilized whereby the accuracy of the determined or measured deformations may be improved.

Instead of light emitting diodes, other indicating means may be utilized, for example strongly colored spots, light reflecting means etc. as the purpose is to define reference points detectable to the camera 41.

The mirror 45 may be placed at other angles than the illustrated 45°, whereby corresponding alterations to the configuration may have to be performed, however.

Other means of arranging the light emitting devices may be utilized, for example a number of light emitting devices arranged in two levels in order to provide the necessary information to the camera. Further, additional cameras such as two, three or more, may be provided and correspond to a light emitting device arrangement, whereby the necessary information concerning the deformation in two or more dimensions may be provided.

Fig. 5 shows a block diagram illustrating an embodiment of the method and apparatus, whereby the deformations of a bone, and in particular a healing bone, can be determined and whereby the strength and/or the state of healing can be determined.

The signals 51a – 51n from a number of sets of measuring arrangements comprising for example video cameras as measurement tools are led to a processing unit 52, wherein the signals are processed in order to determine actual deformations and/or values corresponding to such deformations. When the measuring arrangement is configured as described in connection with ~~f~~Fig. 3, at least two measuring arrangements are required while an arrangement as described in connection with ~~f~~Fig. 4 may work satisfactorily with only one measuring arrangement.

The processing unit 52 may be connected to a indicating device 53, for example a scale, on which the patient and/or the physician may observe the magnitude of the resulting deformations. Further, the signals 57 from the processing unit 52 are led to a further processing unit 59 which will be described later.

Signals 54a – 54m, for example signals from a weight cell, a force measuring device, a torque measuring device etc., are led to a force signal processing unit 55. This unit may be connected to a force indicator 56, for example in the form of a scale, which allows the patient and/or the physician to observe the force and the load placed on the bone by the patient, for example. Hereby, it may be avoided that an excessive load or force is exerted on the healing bone or bones. The force signal processing unit 55 may process the incoming signals to calculate the actual force which acts on

the bone or bones and may indicate this force in normalized and/or standardized values, e.g. the vertical force, horizontal force, force in a forward direction etc. The resulting signals 58 from the force signal processing unit 55 are led to the additional processing unit 59 which serves to correlate the measured and/or detected deformations with the load or force exerted on the bone or bones. The results 60 hereof may be indicated on a display (not shown), for example in graphical form or as tables, or/and they may be printed. Further, the results may be stored by means of a storing unit 61, whereby the results may be used in connection with testing of the healing state of bones on other patients, on different bones of the same patient, or in connection with subsequent testing of the same bone or bones of the same patient. Further, the test results may be used as e.g. statistical data in connection with improvements of methods for assessing the healing state of bones.

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SUBSTITUTE SPECIFICATION (CLEAN VERSION)

METHOD OF MEASURING BONE STRENGTH, APPARATUS FOR MEASURING BONE STRENGTH AND FIXATION DEVICE

BACKGROUND OF THE INVENTION

Field of the invention

The invention relates to a method of measuring the strength or stiffness of a bone, an apparatus for measuring the strength or stiffness of a bone and an external fixator for supporting a bone.

Description of Related Art

When a bone, for example a bone in a limb of an animal or a human being, is healing after a fracture, it is known to support such a bone with an external holding device called a fixation device or a fixator. Such a fixator serves to fixate the ends of the bone in relation to each other as well as to carry the load or part of the load which a patient may have to place on the bone during the healing process.

Further, it is known to use such a fixator when extending the length of a bone. This is done by performing an osteotomy, i.e. by performing a substantially transversal cut in the bone, by preferably gradually pulling the ends of the bone apart at a predetermined and limited distance and by fixating the ends of the bone adjacently to each other. Hereby, the space between the ends of the bone will gradually be filled with new bone material, after which the ends of the bone may be pulled apart once again in order to increase the length of the bone even further. Eventually, when the bone has reached the required length and developed the necessary strength and stiffness, the external fixating device, the fixator, which may be unilateral, semicircular or circular, may be removed.

In order to determine the right time for removal of the fixator during a healing process and/or during a revalidation process, it is known to evaluate the consolidation of the fracture or the osteotomy by using radiography, e.g. x-ray-technology, DEXA (dual or double energy x-ray absorption), CT-scanning, or other similar methods such as ultrasound, other scanning methods etc. However, these methods rely on the assessment skills and experience of the person or persons, e.g. the physician or the surgeon, using the method. Thus, an accurate and objective determination can not be made by using this method. Further, it is known to perform a purely physical examination in order to determine the strength or stiffness of a healing bone, e.g. by having the physician grab the limb and physically try to flex, bend and/or twist the limb in order to assess the state of healing. Of course, this is based solely on the assessment skills and experience of the person or persons, e.g. the physician, carrying out the examination.

In this context, it is understood that the terms stiffness and strength of a bone will refer to the same physical parameter of a bone, e.g. the resistance to deformation once a force or load is placed on the bone.

Further, it is known to detect or measure the deformation of a part using a fixator, when a load is placed on the assembly of the bone and the fixator.

An example of this is described in US 5,792,076, which relates to a fixation device having an elongated optical fiber. The fixation device is affixed to a patient's bone by pins attached to a fixation bar. The fixation bar comprises the elongated optical fiber and light is transmitted through the optical fiber to an exit point where the intensity is measured. As the bone fracture is gradually healing, the load, e.g. the weight or part of the weight of the patient, will gradually be transferred from the fixation bar to the bone of the patient, giving rise to a change in the intensity of the transmitted light. Thus, a physician will be able to assess when the fracture has fully healed by observing the change in the light intensity.

This method, however, suffers from the disadvantage that the fixation bar is an integral part of the system of which the strength is evaluated. Thus, the result of the assessments will not necessarily provide a true picture of the strength of the bone. Further, the assessment is given of a deformation of the fixation bar which is mounted unilaterally. Thus, the deformation of the bone in other dimensions will not be evaluated by this method. Further, in many cases, a fractured bone will have one or more neighboring bones, for example in a lower arm or in a lower leg, which means that when a limb is subjected to a certain load or a strain, this load or strain will be dissipated on the bones in the limb and possibly also on any fixation devices used. Thus, the load, force or strain placed on the fractured bone will be difficult to determine on the basis of the load placed on the limb, and the deformation of the bone and the limb will depend on the assembly as a whole. Thus, for example, a load on a limb in an axial direction may of course result in an axial deformation of the fracture bone, but it may also result in an angular deformation, e.g. a twisting motion, and a bending deformation.

It is also known to use means for measuring or detecting the strain and/or deformation of the bone, wherein the means is attached to the bone or the limb.

An example of such a method is described in EP 0 324 279 A1, wherein the bending of e.g. a lower leg having a healing fracture is measured by means of a goniometer. Bone pins are placed on each side of the fracture site, and a goniometer is attached to these pins and positioned substantially parallelly with the axis of the bone. The deformation, i.e. the bending of the bone, is measured while simultaneously applying force to the bone of the patient. This force, which may be constituted by the weight of the limb, e.g. the lower leg, may be measured by a scale placed under one end of the limb, e.g. under the heel of the patient.

Another example of such a system is described in US 5,339,533.

Both systems also suffer from the disadvantages described above with the exception of the fixation bar which is not applied in these systems when determining the

strength of the bone. However, by using these systems, only the bending deformation of the bone will be determined. Thus, the true strength of the bone will not be evaluated.

A further prior art fixation device is described in WO 98/00062. This fixation device has two ring-shaped members attached to a fractured bone by pins on each side of the fracture. The two ring-shaped members are connected to each other by connecting studs in order to support the bone. One of the ring members comprises a first and a second element which may be rotated in relation to each other. The first element carries the connecting studs while the second element is connected to the pins. The two elements may be rotated in relation to each other when a force is exerted on the bone, i.e. the healing fracture, via one of the elements whereby the two bone parts will be subject to a torque attempting to twist the two bone parts in relation to each other. The extent of the movement, e.g. the angle, and the exerted force corresponding to the torque, may be measured in order to obtain values reflecting the strength of the bone.

By this system, only the torsional strength of the bone, e.g. the healing bone, may be determined which may not provide a true picture of the strength of the healing bone, e.g. the state of healing, as the resistance to axial deformation and bending deformation will not be detected and these resistances may not be proportional to the resistance of a torsional force. Thus, the true state of the healing process and the true strength of the bone, e.g. the healing bone fracture, may not be determined by this method.

The prior art methods and systems for determining the strength or stiffness of a healing bone generally suffer from the drawback that the strength of the healing bone will not be determined with the required accuracy. Thus, the optimal time for removal of a fixation device cannot be determined by using these methods and systems.

When trying to decide when a healing bone, e.g. a bone healing after a fracture or after an ostetomy performed in order to increase, reduce or alter the angling of the bone, has gained sufficient strength to allow a fixation device, e.g. an external fixation device to be loosened or removed, it is important to find the optimal or nearly optimal time for loosening or removal.

If the fixation device is removed too soon, the healing bone may be refractured, whereby the patient will suffer additional discomfort and possibly complications in the healing process. Hereby, the healing period will be extended and the health service as well as society in general will have to spend unnecessary resources, e.g. loss of work, occupation of hospital resources etc., and the patient will suffer from additional discomfort and loss of income.

Therefore, there has been a tendency to extend the period of which a fixation device is used until it is safe to assume that a refracture will not occur. This tendency is enhanced by the fact that existing methods of determining the state of a healing bone involve some inaccuracies. Consequently, in most cases, the fixation device is left on the patient for a longer period of time than is necessary in order to ensure that a refracture will not occur.

As the healing process has proven to be accelerated when the fracture is subjected to normal or near-normal load situations as soon as it is deemed safe, the healing process as a whole is reduced. However, as there is a tendency to maintain the healing bone supported by the fixator longer than strictly necessary in order to be on the safe side, this will extend the healing and revalidation time leading to unnecessary resource spending, loss of work, unnecessary occupation of hospital and medical resources, loss of income, prolonged discomfort of the patient etc.

Thus, it is an object of the invention to provide an improved method of determining the strength or stiffness of a bone, and in particular a healing bone. A further object of the invention is to provide a method of determining the strength of a bone, and in particular a healing bone, whereby the strength of the bone may be determined with

improved accuracy, whereby an improved method of determining the time for removal of a holding device, and in particular an external holding device, may be provided.

Another object of the invention is to provide an improved apparatus for determining the strength or stiffness of a bone, and in particular a healing bone. A still further object of the invention is to provide an apparatus for determining the strength or stiffness of a bone, and in particular a healing bone, whereby the strength or stiffness of the bone may be determined with improved accuracy, whereby an improved method of determining the time for removal of a holding device, and in particular an external holding device, may be provided.

It is also an object of the invention to provide a fixation device for a healing bone, whereby the fixation device will facilitate improved determination of the strength or stiffness of the bone, e.g. the healing bone.

It is a further object of the invention to provide means for reducing the time during which a patient will have to be equipped with an external fixator, whereby costs involved with healing bones, e.g. bones healing after a fracture or after an osteotomy, will be reduced.

These and other objects are achieved by the invention.

BRIEF SUMMARY OF THE INVENTION

The invention relates to a method of measuring the strength of a bone, in particular a bone healing after a fracture or an osteotomy which has been performed in order to extend, reduce or alter the angle of the bone, whereby external fastening means are attached onto the bone in at least two locations, whereby the external fastening means are provided with means for detection and/or measurement of relative displacement between the at least two external fastening means, whereby the bone is subject to strain, and whereby corresponding measurements and/or detections are

made of the relative displacement by contactless measurement of and/or detection means.

Hereby, a measurement is made which will provide a more accurate assessment of the strength and/or stiffness of a bone as the measuring arrangements will not have any influence on the result of the measurements, e.g. the measuring arrangements will not contribute to the stiffness of the structure, i.e. the bone or bones subject to the measurements. Further, the contactless measuring arrangement will allow increased flexibility when setting up the arrangement and also allow measurements to be performed in more than one dimension.

Measurement and/or detection of the relative displacement may comprise measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement. Hereby, measurements may be made of any deformations induced by any given force or load placed on the bone.

The external fastening means may be part of external fixing means for supporting the bone. Hereby, a flexible and convenient way of obtaining measurements is achieved which are necessary for evaluating the healing state of a bone as fastening means already attached onto the patient may be used when performing the method.

The bone is subjected to strain, preferably by the patient, and the strain is measured, detected and/or visualized. Hereby, deformations may be induced in a convenient manner and the cause of the deformations be documented.

The corresponding measurements and/or detections of the relative displacement and strain on the bone may be correlated and/or recorded, whereby a comparison of the deformations and the causes may be made, whereby an assessment of the strength of the bone may be conveniently performed.

The invention also concerns a method which relates to the measurement of the strength of a bone, in particular a bone healing after a fracture or after an osteotomy,

whereby external fastening means are attached onto the bone in at least two locations, whereby the external fastening means are provided with means for detection and/or measurement of relative displacement between the at least two external fastening means, whereby the bone is subjected to strain, and whereby corresponding measurements and/or detections are made of the relative displacement in at least two dimensions of the strain on the bone.

Hereby, a method is achieved which will provide a more accurate assessment of the strength and/or stiffness of a bone as the measuring arrangements will allow measurements to be performed in more than one dimension providing improved measurements of the induced deformations that those of prior art methods.

The measurement and/or detection of the relative displacement may comprise measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement. Hereby, measurements may be made of any deformations induced by any given force or load placed on the bone.

The external fastening means may be part of external fixing means for supporting the bone. Hereby, a flexible and convenient way of obtaining the measurements necessary for evaluating the healing state of a bone is achieved as fastening means already attached onto the patient may be used when applying the method.

The bone may be subjected to strain by the patient and the strain may be measured, detected and/or visualized. Hereby, deformations may be induced in a convenient manner and the cause of the deformations be documented.

The corresponding measurements and/or detections of the relative displacement and the strain on the bone may be correlated and/or recorded, whereby a comparison of the deformations and the causes may be made, whereby an assessment of the strength of the bone may be conveniently performed.

Further, the invention relates to an apparatus for measurement of the strength of a bone, in particular a bone having a healing osteotomy or a healing bone fracture, the apparatus comprising external fastening means for connection to the bone in at least two locations, the external fastening means being provided with means for detection and/or measurement of relative displacement by contactless measurement and/or detection means between the at least two external fastening means.

Hereby, an apparatus is provided whereby a measurement is made which will provide a more accurate assessment of the strength and/or stiffness of a bone as the measuring arrangements will not have any influence on the result of the measurements, e.g. the measuring arrangements will not contribute to the stiffness of the structure, i.e. the bone or bones subject to the measurements. Further, the contactless measuring arrangement will allow increased flexibility when setting up the arrangement and allow measurements to be performed in more than one dimension by the apparatus.

The apparatus is provided with means for measurement and/or detection of induced strain on the bone. Hereby, the cause of the deformations may be readily documented and utilized in connection with the assessment of the bone strength.

The apparatus may be provided with means for correlating the measurements and/or detections of relative displacement and strain, whereby a comparison of the deformations and the causes may be made by the apparatus, whereby an assessment of the strength of the bone may be conveniently performed on the basis hereof.

The means for contactless measurement and/or detection of relative displacement between the at least two external fastening means may facilitate measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement. Hereby, measurements may be made of any deformations induced by any given force or load placed on the bone.

The external fastening means may be part of external fixing means for supporting the bone. Hereby, an apparatus according to this embodiment may be utilized in a flexible and convenient way to obtain the measurements necessary for assessing the healing state of a bone as fastening means already attached onto the patient may be used in connection with or as part of the apparatus.

The apparatus is provided with means for supporting one or both ends of a limb, for positioning one end of a limb and/or for transferring force to/from the limb to/from measuring means. Hereby, the patient may exert the load or force necessary to induce the deformations of the bone or bones. The weight of a limb alone may constitute a load or the patient may place more or less bodyweight on the limb. When one end of the limb is positioned, preferably by a bracket or similar means, the patient may exert force on the bone in any other direction than the vertical direction, e.g. horizontal direction, attempting to twist the bone etc., whereby more varied deformations may be induced.

The apparatus may comprise means for indicating, visualizing and/or recording the measured and/or detected strain. Hereby, the cause of the deformations may be documented by the apparatus, whereby an assessment of the strength of the bone may be performed by a skilled user.

The apparatus may preferably comprise means for indicating, visualizing and/or recording the measured and/or detected relative displacement, whereby the result of the measurements may be used for immediate or subsequent assessments.

The invention further relates to an apparatus for measurement of the strength of a bone, in particular a bone having a healing osteotomy or a healing bone fracture, the apparatus comprising external fastening means for connection to the bone in at least two locations, the external fastening means being provided with means for detection and/or measurement of relative displacement in at least two dimensions between the at least two external fastening means, and the apparatus being provided with means for measurement and/or detection of an induced strain on the bone.

Hereby, an apparatus is provided by means of which a more accurate assessment of the strength and/or stiffness of a bone may be performed as the measuring arrangements of the apparatus will facilitate measurements in more than one dimension and thus provide improved measurements of the induced deformations than those of prior art apparatuses.

The apparatus may be provided with means for correlating the measurements and/or detections of relative displacement and strain, whereby a comparison of the deformations and the causes may be provided by the apparatus, whereby an assessment of the strength of the bone may be conveniently performed by a skilled person, e.g. a physician.

The means for detection and/or measurement of relative displacement in at least two dimensions between the at least two external fastening means may facilitate measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement. Hereby, measurements may be made of any deformations induced by any given force or load placed on the bone. The means for detection and/or measurement of relative displacement in at least two dimensions may be configured as mechanical measuring means, e.g. slide gauges or other similar means connected to the two external fastening means in such a manner that measurements may be made in two or more dimensions.

The external fastening means may be part of external fixing means for supporting the bone. Hereby, an apparatus according to this embodiment may be utilized in a flexible and convenient way to obtain the measurements necessary for assessing the healing state of a bone as fastening means already attached onto the patient may be used in connection with or as part of the apparatus.

The apparatus may be provided with means for supporting one or both ends of a limb, for positioning one end of a limb and/or for transferring force to/from the limb to/from measuring means. Hereby, the patient may exert the load or force necessary

to induce the deformations of the bone or bones. The weight of a limb may constitute a load alone or the patient may place more or less bodyweight on the limb. When one end of the limb is positioned, preferably by a bracket or similar means, the patient may exert a force on the bone in any other direction than the vertical direction, e.g. horizontal direction, attempting to twist the bone etc., whereby more varied deformations may be induced.

The apparatus may comprise means for indicating, visualizing and/or recording the measured and/or detected strain. Hereby, the cause of the deformations may be documented by the apparatus, whereby an assessment of the strength of the bone may be performed by a skilled user.

The apparatus may comprise means for indicating, visualizing and/or recording the measured and/or detected relative displacement, whereby the result of the measurements may be used for immediate or subsequent assessments.

Finally, the invention also pertains to an external fixation device which relates to an external fixator for supporting a bone, e.g. a bone in a limb of an animal or a human being, the fixator comprising means for fastening onto the bone in at least two locations and connecting means for providing a preferably adjustable connection between the fastening means, wherein the connection means are replaceable and wherein measurement and/or detection means for detection and/or measurement of relative displacement between the at least two external fastening means are attachable to the at least two external fastening means.

Hereby, a fixator for supporting a bone or bones is provided which may also serve as fastening means when performing measurements of the flexibility of the bone. Thus, the measurements and hence the assessment of the healing state of the bone may be performed in a expedient manner when a fixator according to the invention is utilized.

The measurement and/or detection means for detection and/or measurement of relative displacement between the at least two external fastening means are contactless. Hereby, a measurement may be made which will provide a more accurate assessment of the strength and/or stiffness of a bone, as the measuring arrangements will not have any influence on the result of the measurements, e.g. the measuring arrangements will not contribute to the stiffness of the structure, i.e. the bone or bones subject to the measurements. Further, the contactless measuring arrangement will allow increased flexibility when setting up the arrangement and also allow measurements to be performed in more than one dimension.

The measurement and/or detection means for detection and/or measurement of relative displacement between the at least two external fastening means may be configured for detection and/or measurement of relative displacement in at least two dimensions. Hereby, a more accurate assessment of the strength and/or stiffness of a bone may be performed as the measuring arrangements will allow measurements to be performed in more than one dimension and provide better measurements of the induced deformations than those of prior art systems. The means for detection and/or measurement of relative displacement in at least two dimensions may be configured as mechanical measuring means, e.g. slide gauges or other similar means connected to the two external fastening means in such a manner that measurements may be made in two or more dimensions. Other measuring means than purely mechanical ones may be used as well.

The at least two external fastening means may each comprise or be connected to a structural member which surrounds the body part containing the bone at least partly, the preferably adjustable connection between the fastening means being connected to the structural members. Hereby, the fastening means may constitute a firm connection for attachment of the measurement and/or detection means.

The structural members may comprise separate and/or relatively movable parts which may be joined and/or adjusted in order to surround a limb at least partly.

Hereby, the structural members may be used flexibly as they may be adjusted in relation to the actual use as the structural members may be easily attached and removed.

The connection means comprises one, two, three, four or more connecting rods which may preferably be adjustably placed between the at least two fastening means. Hereby, a versatile fixator is achieved which may be used in a wide number of applications.

The measurement and/or detection means for detection and/or measurement of relative displacement between the at least two external fastening means are attachable to the structural members forming part of or being connected to the at least two external fastening means. Hereby, the fastening means may conveniently be fastened onto appropriate places, e.g. the front of the bone, the side etc., and provide a firm connection.

The measurement and/or detection means for detection and/or measurement of relative displacement may be connected to the at least two external fastening means and/or the corresponding structural members by means which also serve as fixation means for the preferably adjustable connection between the fastening means. Hereby, the fastening of the measurement and/or detection means may be performed in a surprisingly simple manner and by means of a minimum of technical means.

The measurement and/or detection means for detection and/or measurement of relative displacement may comprise electrical, magnetic or electromagnetic measurement and/or detection means. Hereby, the fixator may be flexibly used in connection with a number of different measuring arrangements selected according to actual use, actual measurement, and/or processing arrangements and/or other preferences.

The measurement and/or detection means for detection and/or measurement of relative displacement may comprise optical measurement and/or detection means, for example in the form of digital video cameras or light emitting devices such as for example LEDs. Hereby, an advantageous measuring arrangement is achieved which

is relatively easy to install and use and which facilitates effortless use also by person without any particular technical skills.

The measurement and/or detection means for detection and/or measurement of relative displacement may comprise one or more measurement and/or detection means.

The measurement and/or detection means for detection and/or measurement of relative displacement in at least two dimensions comprise two or more measurement and/or detection means placed at a circumferential distance, e.g. in relation to an axis of the bone, whereby the accuracy of the measurements may be enhanced and hence also the accuracy of the assessment of the strength of the bone and consequently the healing state of the bone.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be described below with reference to the drawings of which

Fig. 1	illustrates a bone separated in two parts and deformations of this bone schematically,
Fig. 2	shows a fixation device attached onto the lower leg of a human being,
Fig. 3	illustrates the fixation device shown in Fig. 3 with deformation measuring means attached,
Fig. 4	shows an alternative deformation measuring arrangement, and
Fig. 5	shows a block diagram illustrating the signal processing according to a further embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 illustrates a bone 10, for example a bone of a human being. This bone 10 has been separated in two parts 10a and 10b, for example a proximal part 10a and a distal part 10b. The separation may be due to a fracture or to an osteotomy operation. During healing, the bone will flex at the place of separation when exposed to stress. The

flexing may be illustrated by the two bone part vectors 11a and 11b, extending from an origin 12a and 12b, respectively. The direction of these vectors represents axes of the bone parts 10a and 10b, e.g. local bone axes and not necessarily an axis of the bone 10.

Obviously, the bone parts 10a and 10b will move longitudinally when exposed to stress. For example, the bone parts will move towards each other when subjected to an at least partly longitudinal force, whereby the healing part of the bone will be compressed. This will be indicated by a reduction of the distance 13 between the origins 12a and 12b of the bone part vectors 11a and 11b, respectively.

Further, application of force and/or momentum to the bone 10 may induce a relative rotational movement of the two bone parts 10a and 10b, which is illustrated by a vector 14a and a vector 14b, extending from the origins 11a and 11b, respectively. These vectors 14a and 14b may extend at right angles from the bone part vectors 11a and 11b, respectively, and/or they may extend in one and the same direction, preferably in a direction perpendicular to one or both of the bone part vectors 11a and 11b.

In an unstrained situation, these vectors extend in a reference direction, illustrated by the punctuated lines 15a and 15b, respectively. As one or both of the bone parts may be rotated when strained, angles 16a and 16b between the vector 14a and the reference direction 15a and between the vector 14b and the reference direction 15b respectively, serve to indicate the rotational movement of the bone parts 10a and 10b and hence also the relative rotational displacement of the bone parts.

Finally, application of force and/or momentum to the bone 10 may induce an angular displacement of the bone parts 10a and 10b and hence the bone part vectors 11a and 11b, causing a change of direction of the bone part vectors. These angles may be indicated by the angle of the bone part vectors in relation to a reference direction, or by the angle of the vectors 14a and 14b, respectively, in relation to a reference direction (not shown) in a plane defined by the bone part vector 11a and the vector 14a

and/or the bone part vector 11b and the vector 14b. As will be explained later, the latter of these two methods will be preferable in connection with the invention.

When determining the strength or stiffness of a bone, and in particular a healing bone, it is desirable to be able to determine all the above-defined relative movements, e.g. the change in distance 13, the change in difference between the angles 16a and 16b and the relative change of direction of the bone part vectors 11a and 11b when forces and/or torques may be exerted on a bone, an assembly of bones and/or a limb.

The invention will now be explained further by reference to an external holder or fixator as illustrated in Fig. 2. This holder may be used to support a fractured bone while healing or, as illustrated, for a leg 20 on which an osteotomy is performed in order to extend, reduce or alter the angle of the bone, and to support the bones during the healing process. The external fixator may be unilateral, e.g. support by only one axial supporting bar or rod, semicircular, e.g. support of half a circle surrounding the bone, or circular, e.g. support is essentially circumferentially.

In Fig. 2, the use of the external fixator is illustrated in connection with the lower leg of a human being, but the fixator may obviously also be used in connection with other limbs and/or bones if appropriately modified. Further, an external fixator may be used in connection with animals as well as human beings.

The fixator comprises a number of ring-shaped structural members 21, 22, 26 and 27. The upper ring-shaped member is attached onto one or both bones, the tibia 29 and the fibula 28, of the lower leg by bone pins, bone screws, bone rods or as shown by bone wires 23 connected to the ring-shaped member 21 by connectors 24 and 25. The connectors 24 and 25 allow the bone wire to be fastened onto the ring-shaped member 23 with sufficient tensile strength to assure a rigid connection between the ring-shaped member 21 and the bone or bones 29 and 28.

The ring-shaped member 22 is similarly connected to one or both of the bones 28 and 29 by wires 23 and connectors 24 and 25. The lower ring-shaped members 26 and 27

are fastened onto the lower part of one or both of the bones 29 and 28 in the same fashion.

The upper ring-shaped members 21 and 22 are located above the healing sites 29a and 28a of the tibia 29 and the fibula 28, respectively, and the lower ring-shaped members are located below the healing sites 29a and 28a. Connecting means 30 in the form of connecting rods are placed between the ring-shaped members in order to support the bones, i.e. the leg. The connecting rods are threaded, at least at the ends, whereby they can be connected to the ring-shaped members by nuts. Longer connecting rods 30a are located between the ring-shaped members 22 and 27 and shorter connecting rods 30b are located between the ring-shaped members 21 and 22 and the ring-shaped members 26 and 27.

As the connecting rods are threaded, the distance between the ring-shaped members can be adjusted. The distance between the ring-shaped members 21 and 22 and the ring-shaped members 26 and 27, respectively, can be adjusted in dependency of the actual placing of the corresponding bone wires 23. The distance between ring-shaped members 22 and 27 can be adjusted by the connecting rods 30a in order to fixate the bone parts appropriately in relation to each other.

When the fixator is used in connection with a leg with a (simple) fracture, the fixator can be adjusted to achieve the natural relations between the bone parts, after which the relationship is maintained until the fracture site has healed sufficiently.

When the fixator is used in connection with a more complex fracture or in connection with a bone extension/reduction/re-angling, the connecting rods 30a are initially adjusted to define an appropriate distance between the bone ends, i.e. the fractured bone ends or the separated bone ends, whereby a healing process, e.g. a bone mass producing process, will begin. Once the healing has started, i.e. the production of bone mass, and has reached a certain stage, the connecting rods 30a can be adjusted to pull the bone ends further apart, whereby the healing process will proceed and produce bone mass in the now intermediate space between the bone parts. This may

be repeated until the desired length of the bone or bones has been achieved. A consolidation of the healing site will then have to take place, after which the fixator may be loosened and/or eventually permanently removed.

The stage of the healing process, e.g. the stiffness or strength of the healing fracture site, can be determined as shown in Fig. 3. This figure corresponds to Fig. 2. However, the connecting rods 30a of the fixating device have been loosened (in the early stages of the healing process) or removed, leaving the leg and the bones 29 and 28 unsupported or partially unsupported. A number of light emitting devices such as for example light emitting diodes (LEDs) 31 has been placed on one of the upper ring-shaped members 22. These LEDs are each mounted at one end of a fixture 32, which has attachment means 33 at the other end by which it is connected to the ring-shaped member 22, for example by through-holes in the ring-shaped member.

Correspondingly, a bracket has been mounted on one of the lower ring-shaped members 27. The bracket comprises a number of rods 35 which are attached by clamping means 37 to the ring-shaped member 27 at the lower ends, for example by bolt and nut. At the upper end of the rods 35, a ring-shaped support has been mounted, and a number of mini-cameras 34 have been placed on the support 35 and/or the rods 35. The cameras, which may be digital video cameras such as USB-cameras, are placed in such a manner that they are located in the proximity of the light emitting devices 31.

When a load, a force and/or a torque is exerted upon the leg 20, the bones will be able to flex freely, as the connecting rods have been removed. This flexing will be transferred to corresponding movements of the ring-shaped members 21 and 27 and hence also the light emitting devices 31 and the cameras 34. By reference to Fig. 1 and the corresponding explanation, it is evident that the relative movements of the light emitting devices 31 and the cameras 34 will provide a full and complete picture of the flexing of the bones in all possible dimensions, and when correlated with the load or force placed onto the bone or bones also on the strength of the healing structure, as will be explained at a later point.

For example, an axial deformation will be determined by a vertical change of the position of the image of the light-emitting device 31 on the corresponding camera 34. A rotational flexing will be determined by a horizontal change of the position of the image of the light-emitting device 31 on the corresponding camera 34, and as more than one LED/camera arrangement is used, in the example four, a bend, e.g. an angular flexing of the bone, will be detected by a difference in the changes of the positions of the image of the light-emitting device 31 on the corresponding camera 34. It is evident that more than two camera/LED-arrangements of this particular configuration placed at different locations may be necessary to achieve this. However, only one camera/light emitting arrangement will suffice to provide a measurement of the deformations in two or more dimensions as will be described at a later point. Processing of the signals or results from the cameras 34 is necessary in order to obtain results indicating the actual one, two or three-dimensional flexing movements/deformations. Such processing methods are known to persons skilled in the art and will not be described in detail.

Figure 3 shows that four camera/LED-arrangements may be used and evenly distributed on the circular ring-shaped support 36, e.g. with an angle interval of 90°. Other configurations obvious to a skilled person may be used as well, and additional camera/LED-arrangements may be used, e.g. two, three, four, five etc.

Further, it is obvious that the LED-arrangements 32, 33, 34 and the camera arrangements 34, 35, 36, 37 may be configured as units which may be attached onto the corresponding ring-shaped members 22 and 27 as units whereby the placing of the measuring arrangements may be performed in an easy and fast manner.

Fig. 3 illustrates the foot of the patient being placed on a force plate 38 in order to determine the load or force, which is exerted on the leg/bone/bones. This force plate 38 may be constituted by a simple weight, a weight cell or other suitable means. Further arrangements may be configured to measure or determine other forces than substantially vertical forces, e.g. horizontal forces, or torques exerted on the leg. These

arrangements may comprise a bracket or similar means (not illustrated) connected to measurement and/or detection means. For example, these means may be arranged to transfer forces exerted by the patient to the weight cell or other measuring means arranged to measure the vertical forces, whereby these means may also be used to measure or indicate non-vertical loads or forces. Hereby, the patient may be able to exert a twisting torque on the leg, e.g. by attempting to turn his foot. The force in e.g. horizontal direction exerted by the foot may then be measured or detected by the measuring means related to the bracket. Further, the patient may exert bending force on the leg by attempting to push the foot forward, backwards or sideways, whereby the force may be measured or detected by the measuring arrangements in a similar manner.

The force exerted by a patient attempting to turn or twist his foot may also be determined by using for example a electromotor, e.g. an electrodynamic motor, arranged axially beneath the support. When the patient attempts to turn his foot, this will have to be done against a torque exerted by the motor. The torque can be determined, as will be obvious to a skilled person, by knowledge of the motor characteristics and by determining the motor current. Further, the maximum torque may be controlled by controlling the motor current, whereby it can be avoided that the patient may place an excessively large load on the bone, as the motor will just allow further turning when the maximum torque has been reached.

Other safety means may be provided, e.g. audible or visible alarm means which will indicate to the patient and/or to the physician that a certain level of force has been reached which may harm the healing bone. The maximum level or levels of force may be selected and/or adjusted by the physician on the basis of the knowledge of the patient, the state of healing, former tests etc., whereby refractures and other harm to the patient and the healing bone/bones may be avoided. The audible or visible alarm means may also serve to indicate the actual level of force, for example by a frequency increase once the level of force exerted by the patient increases.

Other measuring means obvious to a person skilled in the art may also be utilized.

Another arrangement for measuring the relative flexing movements, e.g. the deformation of a bone, is illustrated in Fig. 4. In this figure, only two ring-shaped structural members 22 and 27 of the fixating device are, of course, fixed onto a bone as described in connection with Figs. 2 and 3 are described. On one on these ring-shaped members 22 in the example, a camera 41 is placed and points towards the other ring-shaped member 27 in the example. On this ring-shaped member 27, a reference device 42, which must be placed in such a manner that it will be in the vision field of the camera 41 in an unstrained situation of the bone, is placed in a similar manner.

The reference device 42 comprises a number of indicator elements in the form of light emitting diodes (LEDs) 43 for positioning the reference device 42 in the right position in relation to the camera 41. These LEDs 43 are placed in a particular pattern, e.g. in parallel rows and columns as illustrated, in order to facilitate the adjustment and positioning of the reference device 42 and/or the camera 41.

Further, the reference device 42 comprises a number of indicator elements in the form of light emitting diodes (LEDs) 44 for detecting the relative movements, i.e. deformations of the bone. These LEDs 44 are placed opposite a mirror 45 which is placed at an angle of for example 45° in relation to the plane at which the LEDs 44 are positioned. By this arrangement, deformations of the bone in one, two or three dimensions can be detected and measured. For example, axial deformation can be detected as the distance between the LEDs 44 is known, whereby relative axial movements may be determined by processing the corresponding video images, e.g. the distances on the images. Further, rotational movements can be detected and measured as the initial positions of the reference device 42 and the LEDs 44 are known in the unrestrained situation. The angular movements can be detected and measured as the mirror 45 is involved, whereby the distance on the image between the rows and/or columns of LEDs 44 will change, i.e. the image of the distance between two rows will be larger in one end than in the other end and vice versa, when a tilt between the two ring-shaped members 22 and 27 is involved. Evidently, process-

ing of the measurements from the camera 41 has to be performed in order to achieve values for the deformations of the bone/bones. Such processing may be performed in a number of ways which will be known to person skilled in the art.

Fig. 4 shows only one set of cameras with a reference device by which it will be possible to determine the deformations of a bone. More than one set of cameras and a reference device may be utilized whereby the accuracy of the determined or measured deformations may be improved.

Instead of light emitting diodes, other indicating means may be utilized, for example strongly colored spots, light reflecting means etc. as the purpose is to define reference points detectable to the camera 41.

The mirror 45 may be placed at other angles than the illustrated 45°, whereby corresponding alterations to the configuration may have to be performed, however.

Other means of arranging the light emitting devices may be utilized, for example a number of light emitting devices arranged in two levels in order to provide the necessary information to the camera. Further, additional cameras such as two, three or more, may be provided and correspond to a light emitting device arrangement, whereby the necessary information concerning the deformation in two or more dimensions may be provided.

Fig. 5 shows a block diagram illustrating an embodiment of the method and apparatus, whereby the deformations of a bone, and in particular a healing bone, can be determined and whereby the strength and/or the state of healing can be determined.

The signals 51a – 51n from a number of sets of measuring arrangements comprising for example video cameras as measurement tools are led to a processing unit 52, wherein the signals are processed in order to determine actual deformations and/or values corresponding to such deformations. When the measuring arrangement is con-

figured as described in connection with Fig. 3, at least two measuring arrangements are required while an arrangement as described in connection with Fig. 4 may work satisfactorily with only one measuring arrangement.

The processing unit 52 may be connected to a indicating device 53, for example a scale, on which the patient and/or the physician may observe the magnitude of the resulting deformations. Further, the signals 57 from the processing unit 52 are led to a further processing unit 59 which will be described later.

Signals 54a – 54m, for example signals from a weight cell, a force measuring device, a torque measuring device etc., are led to a force signal processing unit 55. This unit may be connected to a force indicator 56, for example in the form of a scale, which allows the patient and/or the physician to observe the force and the load placed on the bone by the patient, for example. Hereby, it may be avoided that an excessive load or force is exerted on the healing bone or bones. The force signal processing unit 55 may process the incoming signals to calculate the actual force which acts on the bone or bones and may indicate this force in normalized and/or standardized values, e.g. the vertical force, horizontal force, force in a forward direction etc. The resulting signals 58 from the force signal processing unit 55 are led to the additional processing unit 59 which serves to correlate the measured and/or detected deformations with the load or force exerted on the bone or bones. The results 60 hereof may be indicated on a display (not shown), for example in graphical form or as tables, or/and they may be printed. Further, the results may be stored by means of a storing unit 61, whereby the results may be used in connection with testing of the healing state of bones on other patients, on different bones of the same patient, or in connection with subsequent testing of the same bone or bones of the same patient. Further, the test results may be used as e.g. statistical data in connection with improvements of methods for assessing the healing state of bones.

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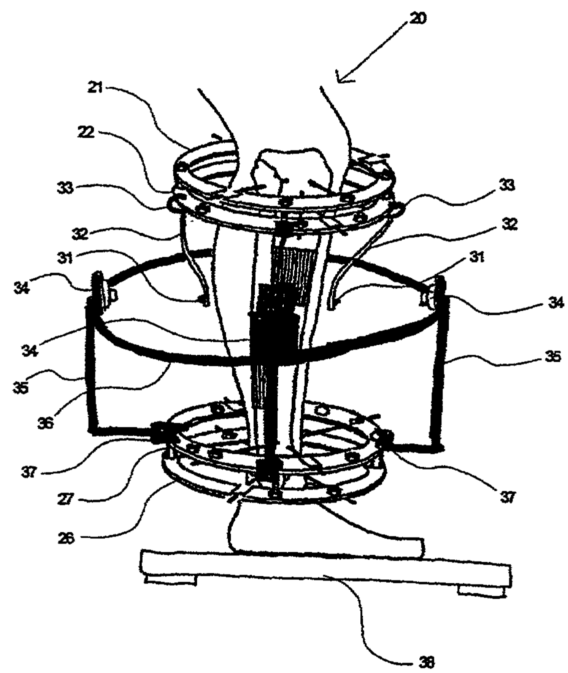
(54) Title: METHOD OF MEASURING BONE STRENGTH, APPARATUS FOR MEASURING BONE STRENGTH AND FIXATION DEVICE



(57) **Abstract:** Method and apparatus for measuring the strength of a bone, in particular a bone healing after a fracture or an osteotomy, whereby external fastening means are attached onto the bone in at least two locations. The external fastening means are provided with means for detection and/or measurement of relative displacement between said at least two external fastening means, the bone is subjected to strain, and corresponding measurements and/or detections are made of the relative displacement by contactless and/or

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WO 01/22892 A1

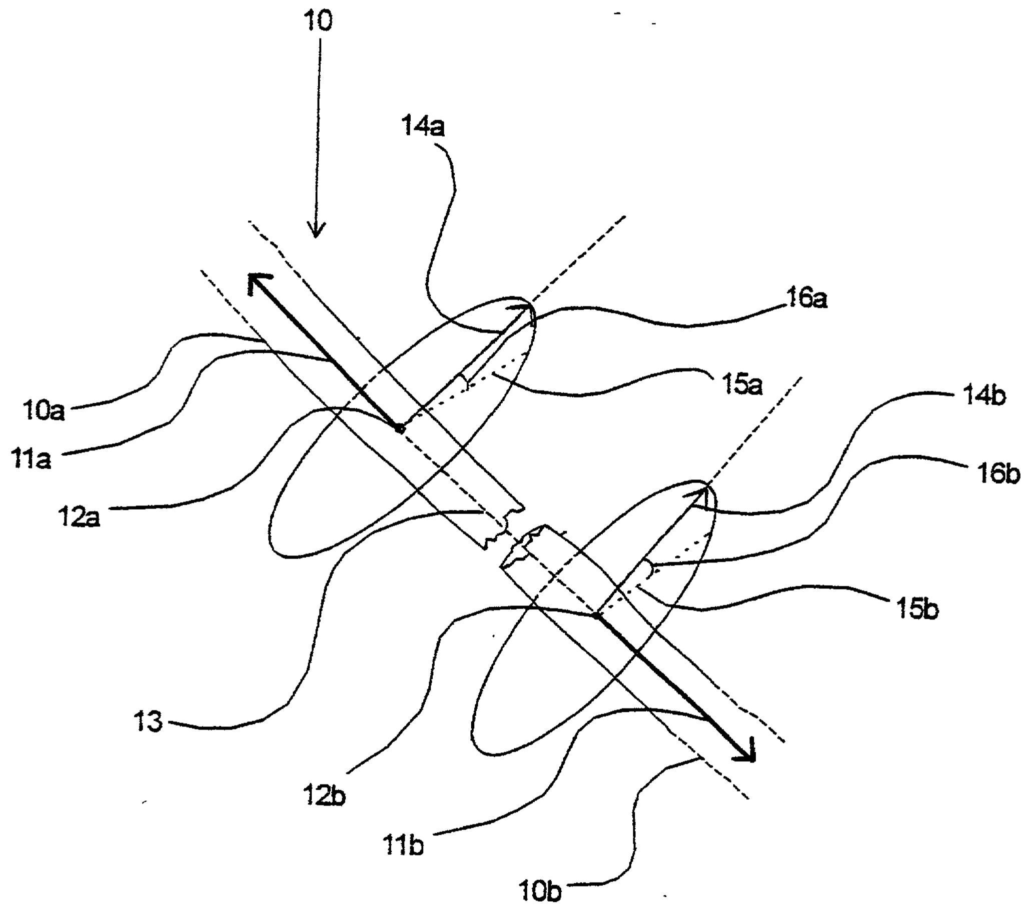

Fig. 1

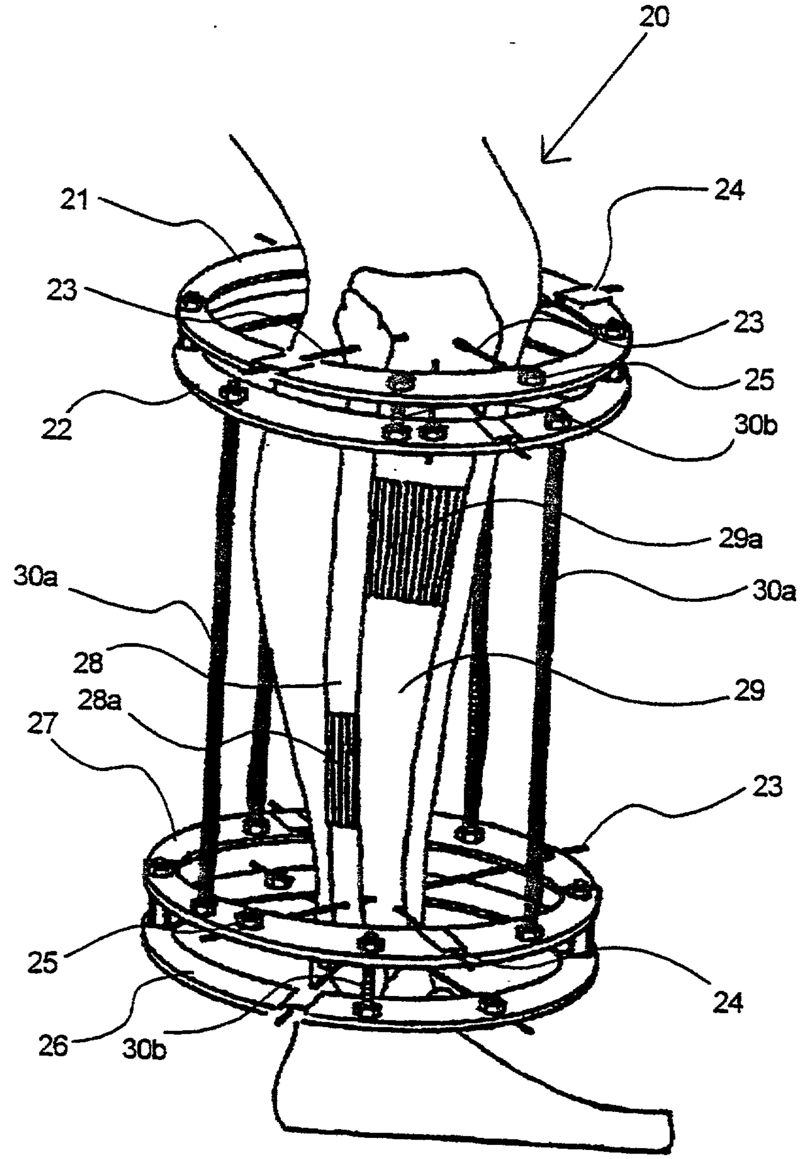

Fig. 2

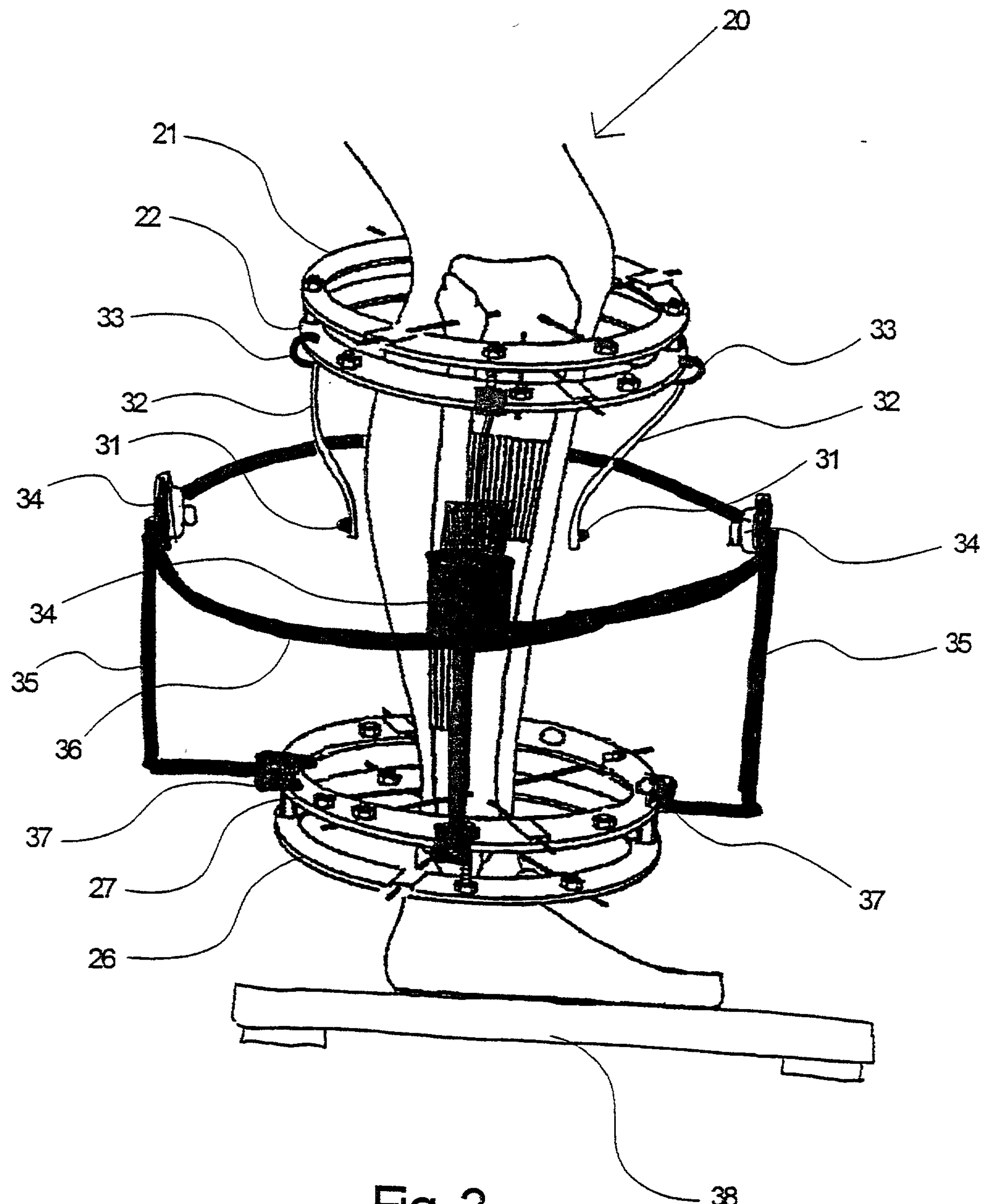

Fig. 3

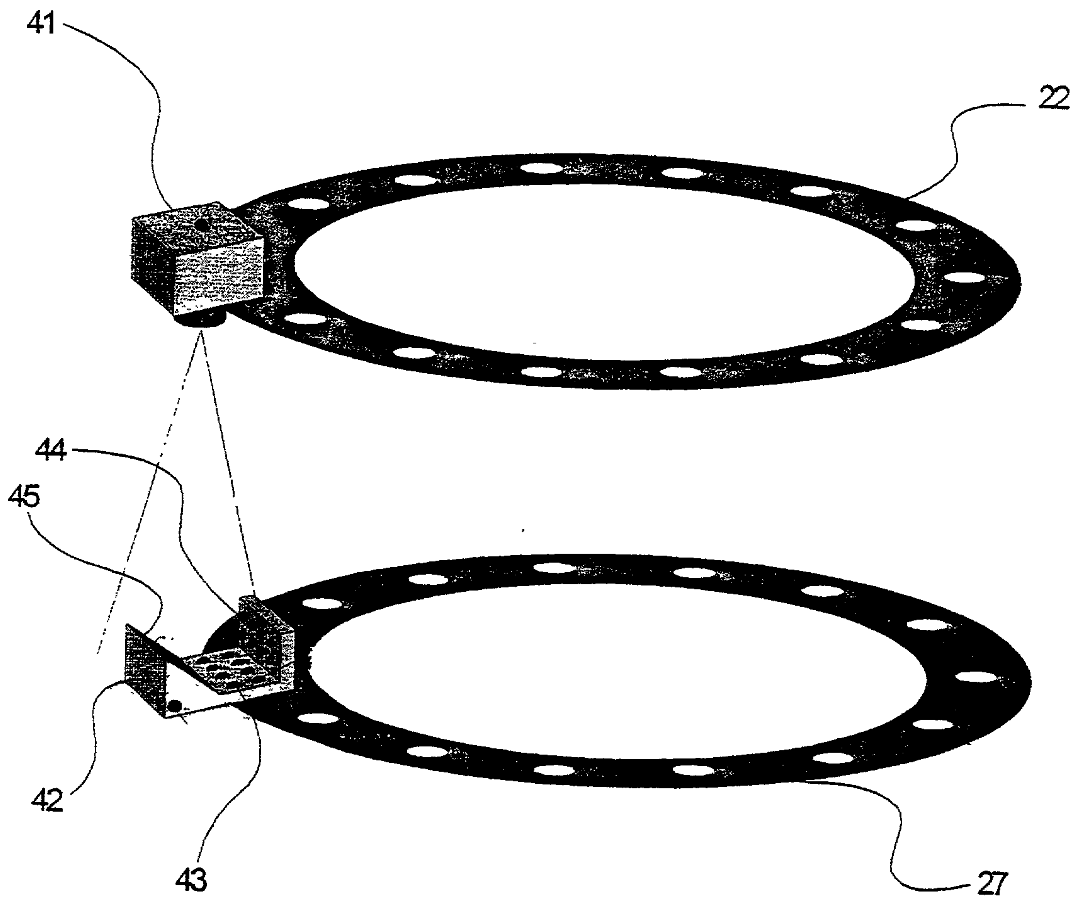

Fig. 4

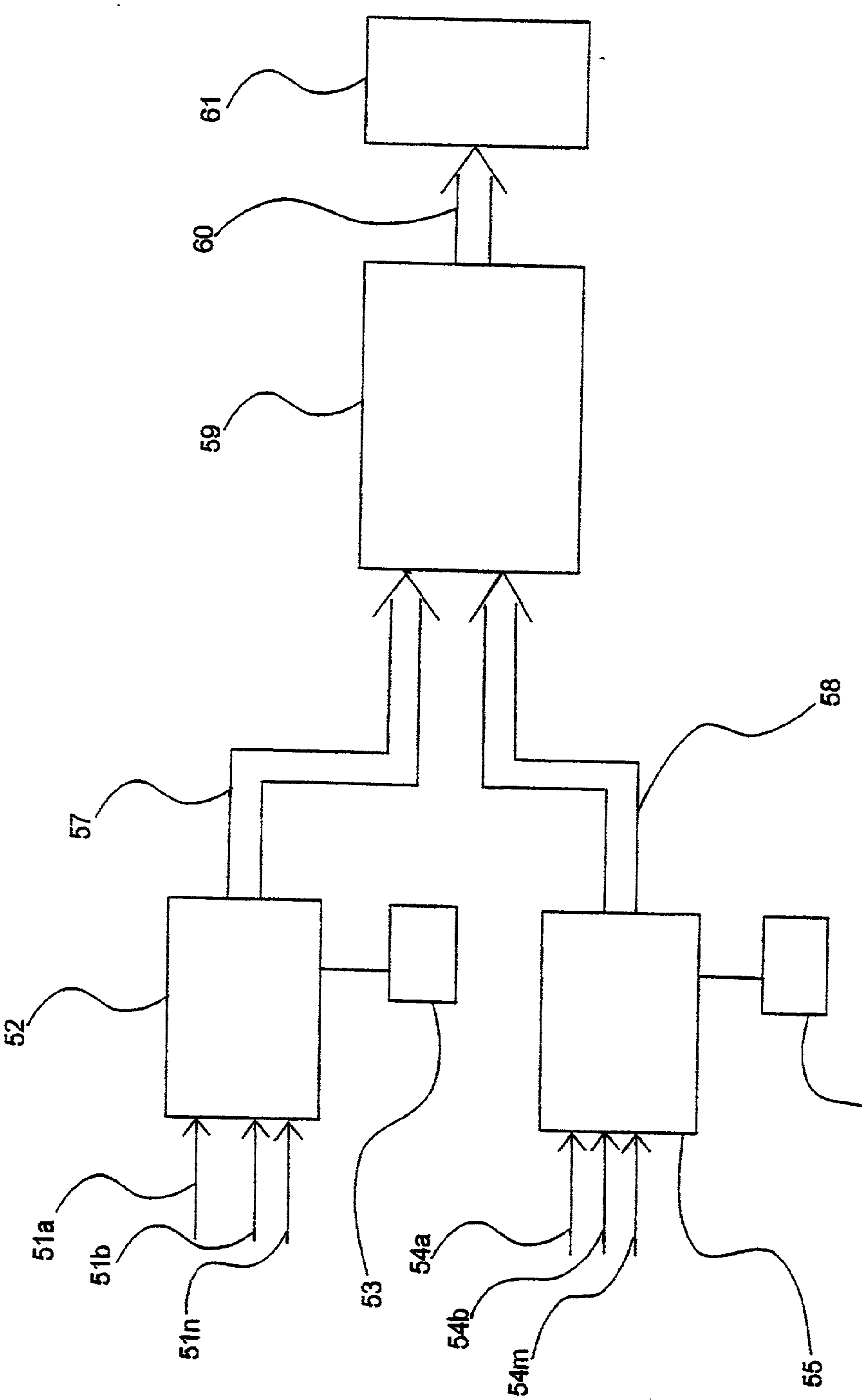

Fig. 5

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METHOD OF MEASURING BONE STRENGTH, APPARATUS FOR MEASURING BONE STRENGTH AND FIXATION DEVICE

Field of the invention

The invention relates to a method of measuring the strength or stiffness of a bone, an apparatus for measuring the strength or stiffness of a bone and an external fixator for supporting a bone.

Background of the invention

When a bone, for example a bone in a limb of an animal or a human being, is healing after a fracture, it is known to support such a bone with an external holding device called a fixation device or a fixator. Such a fixator serves to fixate the ends of the bone in relation to each other as well as to carry the load or part of the load which a patient may have to place on the bone during the healing process.

Further, it is known to use such a fixator when extending the length of a bone. This is done by performing an osteotomy, i.e. by performing a substantially transversal cut in the bone, by preferably gradually pulling the ends of the bone apart at a predetermined and limited distance and by fixating the ends of the bone adjacently to each other. Hereby, the space between the ends of the bone will gradually be filled with new bone material, after which the ends of the bone may be pulled apart once again in order to increase the length of the bone even further. Eventually, when the bone has reached the required length and developed the necessary strength and stiffness, the external fixating device, the fixator, which may be unilateral, semicircular or circular, may be removed.

In order to determine the right time for removal of the fixator during a healing process and/or during a revalidation process, it is known to evaluate the consolidation of the fracture or the osteotomy by using radiography, e.g. x-ray-technology, DEXA (dual or double energy x-ray absorption), CT-scanning, or other similar methods

such as ultrasound, other scanning methods etc. However, these methods rely on the assessment skills and experience of the person or persons, e.g. the physician or the surgeon, using the method. Thus, an accurate and objective determination can not be made by using this method. Further, it is known to perform a purely physical examination in order to determine the strength or stiffness of a healing bone, e.g. by having the physician grab the limb and physically try to flex, bend and/or twist the limb in order to assess the state of healing. Of course, this is based solely on the assessment skills and experience of the person or persons, e.g. the physician, carrying out the examination.

In this context, it is understood that the terms stiffness and strength of a bone will refer to the same physical parameter of a bone, e.g. the resistance to deformation once a force or load is placed on the bone.

Further, it is known to detect or measure the deformation of a part using a fixator, when a load is placed on the assembly of the bone and the fixator.

An example of this is described in US 5,792,076, which relates to a fixation device having an elongated optical fiber. The fixation device is affixed to a patient's bone by pins attached to a fixation bar. The fixation bar comprises the elongated optical fiber and light is transmitted through the optical fiber to an exit point where the intensity is measured. As the bone fracture is gradually healing, the load, e.g. the weight or part of the weight of the patient, will gradually be transferred from the fixation bar to the bone of the patient, giving rise to a change in the intensity of the transmitted light. Thus, a physician will be able to assess when the fracture has fully healed by observing the change in the light intensity.

This method, however, suffers from the disadvantage that the fixation bar is an integral part of the system of which the strength is evaluated. Thus, the result of the assessments will not necessarily provide a true picture of the strength of the bone. Further, the assessment is given of a deformation of the fixation bar which is mounted unilaterally. Thus, the deformation of the bone in other dimensions will not be evalu-

ated by this method. Further, in many cases, a fractured bone will have one or more neighboring bones, for example in a lower arm or in a lower leg, which means that when a limb is subjected to a certain load or a strain, this load or strain will be dissipated on the bones in the limb and possibly also on any fixation devices used. Thus, the load, force or strain placed on the fractured bone will be difficult to determine on the basis of the load placed on the limb, and the deformation of the bone and the limb will depend on the assembly as a whole. Thus, for example, a load on a limb in an axial direction may of course result in an axial deformation of the fracture bone, but it may also result in an angular deformation, e.g. a twisting motion, and a bending deformation.

It is also known to use means for measuring or detecting the strain and/or deformation of the bone, wherein said means is attached to the bone or the limb.

An example of such a method is described in EP 0 324 279 A1, wherein the bending of e.g. a lower leg having a healing fracture is measured by means of a goniometer. Bone pins are placed on each side of the fracture site, and a goniometer is attached to these pins and positioned substantially parallelly with the axis of the bone. The deformation, i.e. the bending of the bone, is measured while simultaneously applying force to the bone of the patient. This force, which may be constituted by the weight of the limb, e.g. the lower leg, may be measured by a scale placed under one end of the limb, e.g. under the heel of the patient.

Another example of such a system is described in US 5,339,533.

Both systems also suffer from the disadvantages described above with the exception of the fixation bar which is not applied in these systems when determining the strength of the bone. However, by using these systems, only the bending deformation of the bone will be determined. Thus, the true strength of the bone will not be evaluated.

A further prior art fixation device is described in WO 98/00062. This fixation device has two ring-shaped members attached to a fractured bone by pins on each side of the fracture. The two ring-shaped members are connected to each other by connecting studs in order to support the bone. One of the ring members comprises a first and a second element which may be rotated in relation to each other. The first element carries the connecting studs while the second element is connected to the pins. The two elements may be rotated in relation to each other when a force is exerted on the bone, i.e. the healing fracture, via one of the elements whereby the two bone parts will be subject to a torque attempting to twist the two bone parts in relation to each other. The extent of the movement, e.g. the angle, and the exerted force corresponding to the torque, may be measured in order to obtain values reflecting the strength of the bone.

By this system, only the torsional strength of the bone, e.g. the healing bone, may be determined which may not provide a true picture of the strength of the healing bone, e.g. the state of healing, as the resistance to axial deformation and bending deformation will not be detected and these resistances may not be proportional to the resistance of a torsional force. Thus, the true state of the healing process and the true strength of the bone, e.g. the healing bone fracture, may not be determined by this method.

The prior art methods and systems for determining the strength or stiffness of a healing bone generally suffer from the drawback that the strength of the healing bone will not be determined with the required accuracy. Thus, the optimal time for removal of a fixation device cannot be determined by using these methods and systems.

When trying to decide when a healing bone, e.g. a bone healing after a fracture or after an ostetomy performed in order to increase, reduce or alter the angling of the bone, has gained sufficient strength to allow a fixation device, e.g. an external fixation device to be loosened or removed, it is important to find the optimal or nearly optimal time for loosening or removal.

If the fixation device is removed too soon, the healing bone may be refractured, whereby the patient will suffer additional discomfort and possibly complications in the healing process. Hereby, the healing period will be extended and the health service as well as society in general will have to spend unnecessary resources, e.g. loss of work, occupation of hospital resources etc., and the patient will suffer from additional discomfort and loss of income.

Therefore, there has been a tendency to extend the period of which a fixation device is used until it is safe to assume that a refracture will not occur. This tendency is enhanced by the fact that existing methods of determining the state of a healing bone involve some inaccuracies. Consequently, in most cases, the fixation device is left on the patient for a longer period of time than is necessary in order to ensure that a refracture will not occur.

As the healing process has proven to be accelerated when the fracture is subjected to normal or near-normal load situations as soon as it is deemed safe, the healing process as a whole is reduced. However, as there is a tendency to maintain the healing bone supported by the fixator longer than strictly necessary in order to be on the safe side, this will extend the healing and revalidation time leading to unnecessary resource spending, loss of work, unnecessary occupation of hospital and medical resources, loss of income, prolonged discomfort of the patient etc.

Thus, it is an object of the invention to provide an improved method of determining the strength or stiffness of a bone, and in particular a healing bone. A further object of the invention is to provide a method of determining the strength of a bone, and in particular a healing bone, whereby the strength of the bone may be determined with improved accuracy, whereby an improved method of determining the time for removal of a holding device, and in particular an external holding device, may be provided.

Another object of the invention is to provide an improved apparatus for determining the strength or stiffness of a bone, and in particular a healing bone. A still further object of the invention is to provide an apparatus for determining the strength or stiffness of a bone, and in particular a healing bone, whereby the strength or stiffness of the bone may be determined with improved accuracy, whereby an improved method of determining the time for removal of a holding device, and in particular an external holding device, may be provided.

It is also an object of the invention to provide a fixation device for a healing bone, whereby the fixation device will facilitate improved determination of the strength or stiffness of the bone, e.g. the healing bone.

It is a further object of the invention to provide means for reducing the time during which a patient will have to be equipped with an external fixator, whereby costs involved with healing bones, e.g. bones healing after a fracture or after an osteotomy, will be reduced.

These and other objects are achieved by the invention.

Summary of the invention

As stated in claim 1, the invention relates to a method of measuring the strength of a bone, in particular a bone healing after a fracture or an osteotomy which has been performed in order to extend, reduce or alter the angle of the bone, whereby external fastening means are attached onto the bone in at least two locations, whereby said external fastening means are provided with means for detection and/or measurement of relative displacement between said at least two external fastening means, whereby the bone is subject to strain, and whereby corresponding measurements and/or detections are made of the relative displacement by contactless measurement of and/or detection means.

Hereby, a measurement is made which will provide a more accurate assessment of the strength and/or stiffness of a bone as the measuring arrangements will not have any influence on the result of the measurements, e.g. the measuring arrangements will not contribute to the stiffness of the structure, i.e. the bone or bones subject to the measurements. Further, the contactless measuring arrangement will allow increased flexibility when setting up the arrangement and also allow measurements to be performed in more than one dimension.

Preferably, as stated in claim 2, measurement and/or detection of the relative displacement may comprise measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement. Hereby, measurements may be made of any deformations induced by any given force or load placed on the bone.

As stated in claim 3, the external fastening means may be part of external fixing means for supporting the bone. Hereby, a flexible and convenient way of obtaining measurements is achieved which are necessary for evaluating the healing state of a bone as fastening means already attached onto the patient may be used when performing the method.

As stated in claim 4, the bone is subjected to strain, preferably by the patient, and the strain is measured, detected and/or visualized. Hereby, deformations may be induced in a convenient manner and the cause of the deformations be documented.

As stated in claim 5, the corresponding measurements and/or detections of the relative displacement and strain on the bone may be correlated and/or recorded, whereby a comparison of the deformations and the causes may be made, whereby an assessment of the strength of the bone may be conveniently performed.

The invention also concerns a method, as stated in claim 6, which relates to the measurement of the strength of a bone, in particular a bone healing after a fracture or after an osteotomy, whereby external fastening means are attached onto the bone in

at least two locations, whereby said external fastening means are provided with means for detection and/or measurement of relative displacement between said at least two external fastening means, whereby the bone is subjected to strain, and whereby corresponding measurements and/or detections are made of the relative displacement in at least two dimensions of the strain on the bone.

Hereby, a method is achieved which will provide a more accurate assessment of the strength and/or stiffness of a bone as the measuring arrangements will allow measurements to be performed in more than one dimension providing improved measurements of the induced deformations that those of prior art methods.

Preferably, as stated in claim 7, the measurement and/or detection of the relative displacement may comprise measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement. Hereby, measurements may be made of any deformations induced by any given force or load placed on the bone.

As stated in claim 8, the external fastening means may be part of external fixing means for supporting the bone. Hereby, a flexible and convenient way of obtaining the measurements necessary for evaluating the healing state of a bone is achieved as fastening means already attached onto the patient may be used when applying the method.

As stated in claim 9, the bone may be subjected to strain by the patient and the strain may be measured, detected and/or visualized. Hereby, deformations may be induced in a convenient manner and the cause of the deformations be documented.

As stated in claim 10, the corresponding measurements and/or detections of the relative displacement and the strain on the bone may be correlated and/or recorded, whereby a comparison of the deformations and the causes may be made, whereby an assessment of the strength of the bone may be conveniently performed.

Further, the invention relates to an apparatus, as claimed in claim 11, for measurement of the strength of a bone, in particular a bone having a healing osteotomy or a healing bone fracture, said apparatus comprising external fastening means for connection to the bone in at least two locations, said external fastening means being provided with means for detection and/or measurement of relative displacement by contactless measurement and/or detection means between said at least two external fastening means.

Hereby, an apparatus is provided whereby a measurement is made which will provide a more accurate assessment of the strength and/or stiffness of a bone as the measuring arrangements will not have any influence on the result of the measurements, e.g. the measuring arrangements will not contribute to the stiffness of the structure, i.e. the bone or bones subject to the measurements. Further, the contactless measuring arrangement will allow increased flexibility when setting up the arrangement and allow measurements to be performed in more than one dimension by the apparatus.

Preferably, as stated in claim 12, the apparatus is provided with means for measurement and/or detection of induced strain on the bone. Hereby, the cause of the deformations may be readily documented and utilized in connection with the assessment of the bone strength.

As stated in claim 13, the apparatus may be provided with means for correlating said measurements and/or detections of relative displacement and strain, whereby a comparison of the deformations and the causes may be made by the apparatus, whereby an assessment of the strength of the bone may be conveniently performed on the basis hereof.

As stated in claim 14, the means for contactless measurement and/or detection of relative displacement between said at least two external fastening means may facilitate measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement. Hereby, measure-

ments may be made of any deformations induced by any given force or load placed on the bone.

As stated in claim 15, the external fastening means may be part of external fixing means for supporting the bone. Hereby, an apparatus according to this embodiment may be utilized in a flexible and convenient way to obtain the measurements necessary for assessing the healing state of a bone as fastening means already attached onto the patient may be used in connection with or as part of the apparatus.

As stated in claim 16, the apparatus is provided with means for supporting one or both ends of a limb, for positioning one end of a limb and/or for transferring force to/from the limb to/from measuring means. Hereby, the patient may exert the load or force necessary to induce the deformations of the bone or bones. The weight of a limb alone may constitute a load or the patient may place more or less bodyweight on the limb. When one end of the limb is positioned, preferably by a bracket or similar means, the patient may exert force on the bone in any other direction than the vertical direction, e.g. horizontal direction, attempting to twist the bone etc., whereby more varied deformations may be induced.

As stated in claim 17, the apparatus may comprise means for indicating, visualizing and/or recording the measured and/or detected strain. Hereby, the cause of the deformations may be documented by the apparatus, whereby an assessment of the strength of the bone may be performed by a skilled user.

As stated in claim 18, the apparatus may preferably comprise means for indicating, visualizing and/or recording the measured and/or detected relative displacement, whereby the result of the measurements may be used for immediate or subsequent assessments.

The invention further relates to an apparatus, as claimed in claim 19, for measurement of the strength of a bone, in particular a bone having a healing osteotomy or a healing bone fracture, said apparatus comprising external fastening means for con-

nection to the bone in at least two locations, said external fastening means being provided with means for detection and/or measurement of relative displacement in at least two dimensions between said at least two external fastening means, and said apparatus being provided with means for measurement and/or detection of an induced strain on the bone.

Hereby, an apparatus is provided by means of which a more accurate assessment of the strength and/or stiffness of a bone may be performed as the measuring arrangements of the apparatus will facilitate measurements in more than one dimension and thus provide improved measurements of the induced deformations than those of prior art apparatuses.

Preferably, as stated in claim 20, the apparatus may be provided with means for correlating said measurements and/or detections of relative displacement and strain, whereby a comparison of the deformations and the causes may be provided by the apparatus, whereby an assessment of the strength of the bone may be conveniently performed by a skilled person, e.g. a physician.

Preferably, as stated in claim 21, the means for detection and/or measurement of relative displacement in at least two dimensions between said at least two external fastening means may facilitate measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement. Hereby, measurements may be made of any deformations induced by any given force or load placed on the bone. The means for detection and/or measurement of relative displacement in at least two dimensions may be configured as mechanical measuring means, e.g. slide gauges or other similar means connected to the two external fastening means in such a manner that measurements may be made in two or more dimensions.

A stated in claim 22, the external fastening means may be part of external fixing means for supporting the bone. Hereby, an apparatus according to this embodiment may be utilized in a flexible and convenient way to obtain the measurements neces-

sary for assessing the healing state of a bone as fastening means already attached onto the patient may be used in connection with or as part of the apparatus.

As stated in claim 23, the apparatus may be provided with means for supporting one or both ends of a limb, for positioning one end of a limb and/or for transferring force to/from the limb to/from measuring means. Hereby, the patient may exert the load or force necessary to induce the deformations of the bone or bones. The weight of a limb may constitute a load alone or the patient may place more or less bodyweight on the limb. When one end of the limb is positioned, preferably by a bracket or similar means, the patient may exert a force on the bone in any other direction than the vertical direction, e.g. horizontal direction, attempting to twist the bone etc., whereby more varied deformations may be induced.

As stated in claim 24, the apparatus may comprise means for indicating, visualizing and/or recording the measured and/or detected strain. Hereby, the cause of the deformations may be documented by the apparatus, whereby an assessment of the strength of the bone may be performed by a skilled user.

As stated in claim 25, the apparatus may comprise means for indicating, visualizing and/or recording the measured and/or detected relative displacement, whereby the result of the measurements may be used for immediate or subsequent assessments.

Finally, the invention also pertains to an external fixation device, as stated in claim 26, which relates to an external fixator for supporting a bone, e.g. a bone in a limb of an animal or a human being, said fixator comprising means for fastening onto the bone in at least two locations and connecting means for providing a preferably adjustable connection between said fastening means, wherein said connection means are replaceable and wherein measurement and/or detection means for detection and/or measurement of relative displacement between said at least two external fastening means are attachable to said at least two external fastening means.

Hereby, a fixator for supporting a bone or bones is provided which may also serve as fastening means when performing measurements of the flexibility of the bone. Thus, the measurements and hence the assessment of the healing state of the bone may be performed in a expedient manner when a fixator according to the invention is utilized.

Preferably, as stated in claim 27, said measurement and/or detection means for detection and/or measurement of relative displacement between said at least two external fastening means are contactless. Hereby, a measurement may be made which will provide a more accurate assessment of the strength and/or stiffness of a bone, as the measuring arrangements will not have any influence on the result of the measurements, e.g. the measuring arrangements will not contribute to the stiffness of the structure, i.e. the bone or bones subject to the measurements. Further, the contactless measuring arrangement will allow increased flexibility when setting up the arrangement and also allow measurements to be performed in more than one dimension.

As stated in claim 28, said measurement and/or detection means for detection and/or measurement of relative displacement between said at least two external fastening means may be configured for detection and/or measurement of relative displacement in at least two dimensions. Hereby, a more accurate assessment of the strength and/or stiffness of a bone may be performed as the measuring arrangements will allow measurements to be performed in more than one dimension and provide better measurements of the induced deformations than those of prior art systems. The means for detection and/or measurement of relative displacement in at least two dimensions may be configured as mechanical measuring means, e.g. slide gauges or other similar means connected to the two external fastening means in such a manner that measurements may be made in two or more dimensions. Other measuring means than purely mechanical ones may be used as well.

As stated in claim 29, said at least two external fastening means may each comprise or be connected to a structural member which surrounds the body part containing the bone at least partly, said preferably adjustable connection between said fastening

means being connected to said structural members. Hereby, the fastening means may constitute a firm connection for attachment of the measurement and/or detection means.

As stated in claim 30, said structural members may comprise separate and/or relatively movable parts which may be joined and/or adjusted in order to surround a limb at least partly. Hereby, the structural members may be used flexibly as they may be adjusted in relation to the actual use as the structural members may be easily attached and removed.

As stated in claim 31, the connection means comprises one, two, three, four or more connecting rods which may preferably be adjustably placed between said at least two fastening means. Hereby, a versatile fixator is achieved which may be used in a wide number of applications.

As stated in claim 32, the measurement and/or detection means for detection and/or measurement of relative displacement between said at least two external fastening means are attachable to said structural members forming part of or being connected to said at least two external fastening means. Hereby, the fastening means may conveniently be fastened onto appropriate places, e.g. the front of the bone, the side etc., and provide a firm connection.

As stated in claim 33, the measurement and/or detection means for detection and/or measurement of relative displacement may be connected to the at least two external fastening means and/or said corresponding structural members by means which also serve as fixation means for said preferably adjustable connection between said fastening means. Hereby, the fastening of the measurement and/or detection means may be performed in a surprisingly simple manner and by means of a minimum of technical means.

As stated in claim 34, the measurement and/or detection means for detection and/or measurement of relative displacement may comprise electrical, magnetic or electro-

magnetic measurement and/or detection means. Hereby, the fixator may be flexibly used in connection with a number of different measuring arrangements selected according to actual use, actual measurement, and/or processing arrangements and/or other preferences.

As stated in claim 35, the measurement and/or detection means for detection and/or measurement of relative displacement may comprise optical measurement and/or detection means, for example in the form of digital video cameras or light emitting devices such as for example LEDs. Hereby, an advantageous measuring arrangement is achieved which is relatively easy to install and use and which facilitates effortless use also by person without any particular technical skills.

As stated in claim 36, the measurement and/or detection means for detection and/or measurement of relative displacement may comprise one or more measurement and/or detection means.

As stated in claim 37, the measurement and/or detection means for detection and/or measurement of relative displacement in at least two dimensions comprise two or more measurement and/or detection means placed at a circumferential distance, e.g. in relation to an axis of the bone, whereby the accuracy of the measurements may be enhanced and hence also the accuracy of the assessment of the strength of the bone and consequently the healing state of the bone.

The figures

The invention will be described below with reference to the drawings of which

fig. 1	illustrates a bone separated in two parts and deformations of this bone schematically,
fig. 2	shows a fixation device attached onto the lower leg of a human being,
fig. 3	illustrates the fixation device shown in fig. 3 with deformation measuring means attached,

fig. 4 shows an alternative deformation measuring arrangement, and

fig. 5 shows a block diagram illustrating the signal processing according to a further embodiment of the invention.

Detailed description

Fig. 1 illustrates a bone 10, for example a bone of a human being. This bone 10 has been separated in two parts 10a and 10b, for example a proximal part 10a and a distal part 10b. The separation may be due to a fracture or to an osteotomy operation. During healing, the bone will flex at the place of separation when exposed to stress. The flexing may be illustrated by the two bone part vectors 11a and 11b, extending from an origin 12a and 12b, respectively. The direction of these vectors represents axes of the bone parts 10a and 10b, e.g. local bone axes and not necessarily an axis of the bone 10.

Obviously, the bone parts 10a and 10b will move longitudinally when exposed to stress. For example, the bone parts will move towards each other when subjected to an at least partly longitudinal force, whereby the healing part of the bone will be compressed. This will be indicated by a reduction of the distance 13 between the origins 12a and 12b of the bone part vectors 11a and 11b, respectively.

Further, application of force and/or momentum to the bone 10 may induce a relative rotational movement of the two bone parts 10a and 10b, which is illustrated by a vector 14a and a vector 14b, extending from the origins 11a and 11b, respectively. These vectors 14a and 14b may extend at right angles from the bone part vectors 11a and 11b, respectively, and/or they may extend in one and the same direction, preferably in a direction perpendicular to one or both of the bone part vectors 11a and 11b.

In an unstrained situation, these vectors extend in a reference direction, illustrated by the punctuated lines 15a and 15b, respectively. As one or both of the bone parts may be rotated when strained, angles 16a and 16b between the vector 14a and the reference direction 15a and between the vector 14b and the reference direction 15b re-

spectively, serve to indicate the rotational movement of the bone parts 10a and 10b and hence also the relative rotational displacement of the bone parts.

Finally, application of force and/or momentum to the bone 10 may induce an angular displacement of the bone parts 10a and 10b and hence the bone part vectors 11a and 11b, causing a change of direction of the bone part vectors. These angles may be indicated by the angle of the bone part vectors in relation to a reference direction, or by the angle of the vectors 14a and 14b, respectively, in relation to a reference direction (not shown) in a plane defined by the bone part vector 11a and the vector 14a and/or the bone part vector 11b and the vector 14b. As will be explained later, the latter of these two methods will be preferable in connection with the invention.

When determining the strength or stiffness of a bone, and in particular a healing bone, it is desirable to be able to determine all the above-defined relative movements, e.g. the change in distance 13, the change in difference between the angles 16a and 16b and the relative change of direction of the bone part vectors 11a and 11b when forces and/or torques may be exerted on a bone, an assembly of bones and/or a limb.

The invention will now be explained further by reference to an external holder or fixator as illustrated in fig. 2. This holder may be used to support a fractured bone while healing or, as illustrated, for a leg 20 on which an osteotomy is performed in order to extend, reduce or alter the angle of the bone, and to support the bones during the healing process. The external fixator may be unilateral, e.g. support by only one axial supporting bar or rod, semicircular, e.g. support of half a circle surrounding the bone, or circular, e.g. support is essentially circumferentially.

In fig. 2, the use of the external fixator is illustrated in connection with the lower leg of a human being, but the fixator may obviously also be used in connection with other limbs and/or bones if appropriately modified. Further, an external fixator may be used in connection with animals as well as human beings.

The fixator comprises a number of ring-shaped structural members 21, 22, 26 and 27. The upper ring-shaped member is attached onto one or both bones, the tibia 29 and the fibula 28, of the lower leg by bone pins, bone screws, bone rods or as shown by bone wires 23 connected to the ring-shaped member 21 by connectors 24 and 25. The connectors 24 and 25 allow the bone wire to be fastened onto the ring-shaped member 23 with sufficient tensile strength to assure a rigid connection between the ring-shaped member 21 and the bone or bones 29 and 28.

The ring-shaped member 22 is similarly connected to one or both of the bones 28 and 29 by wires 23 and connectors 24 and 25. The lower ring-shaped members 26 and 27 are fastened onto the lower part of one or both of the bones 29 and 28 in the same fashion.

The upper ring-shaped members 21 and 22 are located above the healing sites 29a and 28a of the tibia 29 and the fibula 28, respectively, and the lower ring-shaped members are located below the healing sites 29a and 28a. Connecting means 30 in the form of connecting rods are placed between the ring-shaped members in order to support the bones, i.e. the leg. The connecting rods are threaded, at least at the ends, whereby they can be connected to the ring-shaped members by nuts. Longer connecting rods 30a are located between the ring-shaped members 22 and 27 and shorter connecting rods 30b are located between the ring-shaped members 21 and 22 and the ring-shaped members 26 and 27.

As the connecting rods are threaded, the distance between the ring-shaped members can be adjusted. The distance between the ring-shaped members 21 and 22 and the ring-shaped members 26 and 27, respectively, can be adjusted in dependency of the actual placing of the corresponding bone wires 23. The distance between ring-shaped members 22 and 27 can be adjusted by the connecting rods 30a in order to fixate the bone parts appropriately in relation to each other.

When the fixator is used in connection with a leg with a (simple) fracture, the fixator can be adjusted to achieve the natural relations between the bone parts, after which the relationship is maintained until the fracture site has healed sufficiently.

When the fixator is used in connection with a more complex fracture or in connection with a bone extension/reduction/re-angling, the connecting rods 30a are initially adjusted to define an appropriate distance between the bone ends, i.e. the fractured bone ends or the separated bone ends, whereby a healing process, e.g. a bone mass producing process, will begin. Once the healing has started, i.e. the production of bone mass, and has reached a certain stage, the connecting rods 30a can be adjusted to pull the bone ends further apart, whereby the healing process will proceed and produce bone mass in the now intermediate space between the bone parts. This may be repeated until the desired length of the bone or bones has been achieved. A consolidation of the healing site will then have to take place, after which the fixator may be loosened and/or eventually permanently removed.

The stage of the healing process, e.g. the stiffness or strength of the healing fracture site, can be determined as shown in fig. 3. This figure corresponds to fig. 2. However, the connecting rods 30a of the fixating device have been loosened (in the early stages of the healing process) or removed, leaving the leg and the bones 29 and 28 unsupported or partially unsupported. A number of light emitting devices such as for example light emitting diodes (LEDs) 31 has been placed on one of the upper ring-shaped members 22. These LEDs are each mounted at one end of a fixture 32, which has attachment means 33 at the other end by which it is connected to the ring-shaped member 22, for example by through-holes in the ring-shaped member.

Correspondingly, a bracket has been mounted on one of the lower ring-shaped members 27. The bracket comprises a number of rods 35 which are attached by clamping means 37 to the ring-shaped member 27 at the lower ends, for example by bolt and nut. At the upper end of the rods 35, a ring-shaped support has been mounted, and a number of mini-cameras 34 have been placed on the support 35 and/or the rods 35. The cameras, which may be digital video cameras such as USB-cameras, are placed

in such a manner that they are located in the proximity of the light emitting devices 31.

When a load, a force and/or a torque is exerted upon the leg 20, the bones will be able to flex freely, as the connecting rods have been removed. This flexing will be transferred to corresponding movements of the ring-shaped members 21 and 27 and hence also the light emitting devices 31 and the cameras 34. By reference to fig. 1 and the corresponding explanation, it is evident that the relative movements of the light emitting devices 31 and the cameras 34 will provide a full and complete picture of the flexing of the bones in all possible dimensions, and when correlated with the load or force placed onto the bone or bones also on the strength of the healing structure, as will be explained at a later point.

For example, an axial deformation will be determined by a vertical change of the position of the image of the light-emitting device 31 on the corresponding camera 34. A rotational flexing will be determined by a horizontal change of the position of the image of the light-emitting device 31 on the corresponding camera 34, and as more than one LED/camera arrangement is used, in the example four, a bend, e.g. an angular flexing of the bone, will be detected by a difference in the changes of the positions of the image of the light-emitting device 31 on the corresponding camera 34. It is evident that more than two camera/LED-arrangements of this particular configuration placed at different locations may be necessary to achieve this. However, only one camera/light emitting arrangement will suffice to provide a measurement of the deformations in two or more dimensions as will be described at a later point. Processing of the signals or results from the cameras 34 is necessary in order to obtain results indicating the actual one, two or three-dimensional flexing movements/deformations. Such processing methods are known to persons skilled in the art and will not be described in detail.

Figure 3 shows that four camera/LED-arrangements may be used and evenly distributed on the circular ring-shaped support 36, e.g. with an angle interval of 90°. Other

configurations obvious to a skilled person may be used as well, and additional camera/LED-arrangements may be used, e.g. two, three, four, five etc.

Further, it is obvious that the LED-arrangements 32, 33, 34 and the camera arrangements 34, 35, 36, 37 may be configured as units which may be attached onto the corresponding ring-shaped members 22 and 27 as units whereby the placing of the measuring arrangements may be performed in an easy and fast manner.

Fig. 3 illustrates the foot of the patient being placed on a force plate 38 in order to determine the load or force, which is exerted on the leg/bone/bones. This force plate 38 may be constituted by a simple weight, a weight cell or other suitable means. Further arrangements may be configured to measure or determine other forces than substantially vertical forces, e.g. horizontal forces, or torques exerted on the leg. These arrangements may comprise a bracket or similar means (not illustrated) connected to measurement and/or detection means. For example, these means may be arranged to transfer forces exerted by the patient to the weight cell or other measuring means arranged to measure the vertical forces, whereby these means may also be used to measure or indicate non-vertical loads or forces. Hereby, the patient may be able to exert a twisting torque on the leg, e.g. by attempting to turn his foot. The force in e.g. horizontal direction exerted by the foot may then be measured or detected by the measuring means related to the bracket. Further, the patient may exert bending force on the leg by attempting to push the foot forward, backwards or sideways, whereby the force may be measured or detected by the measuring arrangements in a similar manner.

The force exerted by a patient attempting to turn or twist his foot may also be determined by using for example a electromotor, e.g. an electrodynamic motor, arranged axially beneath the support. When the patient attempts to turn his foot, this will have to be done against a torque exerted by the motor. The torque can be determined, as will be obvious to a skilled person, by knowledge of the motor characteristics and by determining the motor current. Further, the maximum torque may be controlled by controlling the motor current, whereby it can be avoided that the patient may place

an excessively large load on the bone, as the motor will just allow further turning when the maximum torque has been reached.

Other safety means may be provided, e.g. audible or visible alarm means which will indicate to the patient and/or to the physician that a certain level of force has been reached which may harm the healing bone. The maximum level or levels of force may be selected and/or adjusted by the physician on the basis of the knowledge of the patient, the state of healing, former tests etc., whereby refractures and other harm to the patient and the healing bone/bones may be avoided. The audible or visible alarm means may also serve to indicate the actual level of force, for example by a frequency increase once the level of force exerted by the patient increases.

Other measuring means obvious to a person skilled in the art may also be utilized.

Another arrangement for measuring the relative flexing movements, e.g. the deformation of a bone, is illustrated in fig. 4. In this figure, only two ring-shaped structural members 22 and 27 of the fixating device are, of course, fixed onto a bone as described in connection with fig. 2 and 3 are described. On one on these ring-shaped members 22 in the example, a camera 41 is placed and points towards the other ring-shaped member 27 in the example. On this ring-shaped member 27, a reference device 42, which must be placed in such a manner that it will be in the vision field of the camera 41 in an unstrained situation of the bone, is placed in a similar manner.

The reference device 42 comprises a number of indicator elements in the form of light emitting diodes (LEDs) 43 for positioning the reference device 42 in the right position in relation to the camera 41. These LEDs 43 are placed in a particular pattern, e.g. in parallel rows and columns as illustrated, in order to facilitate the adjustment and positioning of the reference device 42 and/or the camera 41.

Further, the reference device 42 comprises a number of indicator elements in the form of light emitting diodes (LEDs) 44 for detecting the relative movements, i.e. deformations of the bone. These LEDs 44 are placed opposite a mirror 45 which is

placed at an angle of for example 45° in relation to the plane at which the LEDs 44 are positioned. By this arrangement, deformations of the bone in one, two or three dimensions can be detected and measured. For example, axial deformation can be detected as the distance between the LEDs 44 is known, whereby relative axial movements may be determined by processing the corresponding video images, e.g. the distances on the images. Further, rotational movements can be detected and measured as the initial positions of the reference device 42 and the LEDs 44 are known in the unrestrained situation. The angular movements can be detected and measured as the mirror 45 is involved, whereby the distance on the image between the rows and/or columns of LEDs 44 will change, i.e. the image of the distance between two rows will be larger in one end than in the other end and vice versa, when a tilt between the two ring-shaped members 22 and 27 is involved. Evidently, processing of the measurements from the camera 41 has to be performed in order to achieve values for the deformations of the bone/bones. Such processing may be performed in a number of ways which will be known to person skilled in the art.

Fig. 4 shows only one set of cameras with a reference device by which it will be possible to determine the deformations of a bone. More than one set of cameras and a reference device may be utilized whereby the accuracy of the determined or measured deformations may be improved.

Instead of light emitting diodes, other indicating means may be utilized, for example strongly colored spots, light reflecting means etc. as the purpose is to define reference points detectable to the camera 41.

The mirror 45 may be placed at other angles than the illustrated 45°, whereby corresponding alterations to the configuration may have to be performed, however.

Other means of arranging the light emitting devices may be utilized, for example a number of light emitting devices arranged in two levels in order to provide the necessary information to the camera. Further, additional cameras such as two, three or more, may be provided and correspond to a light emitting device arrangement,

whereby the necessary information concerning the deformation in two or more dimensions may be provided.

Fig. 5 shows a block diagram illustrating an embodiment of the method and apparatus, whereby the deformations of a bone, and in particular a healing bone, can be determined and whereby the strength and/or the state of healing can be determined.

The signals 51a – 51n from a number of sets of measuring arrangements comprising for example video cameras as measurement tools are led to a processing unit 52, wherein the signals are processed in order to determine actual deformations and/or values corresponding to such deformations. When the measuring arrangement is configured as described in connection with fig. 3, at least two measuring arrangements are required while an arrangement as described in connection with fig. 4 may work satisfactorily with only one measuring arrangement.

The processing unit 52 may be connected to a indicating device 53, for example a scale, on which the patient and/or the physician may observe the magnitude of the resulting deformations. Further, the signals 57 from the processing unit 52 are led to a further processing unit 59 which will be described later.

Signals 54a – 54m, for example signals from a weight cell, a force measuring device, a torque measuring device etc., are led to a force signal processing unit 55. This unit may be connected to a force indicator 56, for example in the form of a scale, which allows the patient and/or the physician to observe the force and the load placed on the bone by the patient, for example. Hereby, it may be avoided that an excessive load or force is exerted on the healing bone or bones. The force signal processing unit 55 may process the incoming signals to calculate the actual force which acts on the bone or bones and may indicate this force in normalized and/or standardized values, e.g. the vertical force, horizontal force, force in a forward direction etc. The resulting signals 58 from the force signal processing unit 55 are led to the additional processing unit 59 which serves to correlate the measured and/or detected deforma-

tions with the load or force exerted on the bone or bones. The results 60 hereof may be indicated on a display (not shown), for example in graphical form or as tables, or/and they may be printed. Further, the results may be stored by means of a storing unit 61, whereby the results may be used in connection with testing of the healing state of bones on other patients, on different bones of the same patient, or in connection with subsequent testing of the same bone or bones of the same patient. Further, the test results may be used as e.g. statistical data in connection with improvements of methods for assessing the healing state of bones.

Patent Claims

1. Method of measuring the strength of a bone, in particular a bone healing after a fracture or an osteotomy whereby external fastening means are attached onto the bone in at least two locations, whereby said external fastening means are provided with means for detection and/or measurement of relative displacement between said at least two external fastening means, whereby the bone is subjected to strain, and whereby corresponding measurements and/or detections are made of the relative displacement by contactless measurement and/or detection means.

2. Method according to claim 1, characterized in that measurement and/or detection of the relative displacement comprises measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement.

3. Method according to claim 1 or 2, characterized in that the external fastening means are part of external fixing means for supporting the bone.

4. Method according to claim 1, 2 or 3, characterized in that the bone is subjected to strain, preferably by the patient, and in that the strain is measured, detected and/or visualized.

5. Method according to one or more of claims 1 - 4, characterized in that the corresponding measurements and/or detections of the relative displacement and the strain on the bone are correlated and/or recorded.

6. Method of measuring the strength of a bone, in particular a bone healing after a fracture or an osteotomy, whereby external fastening means are attached onto the bone in at least two locations, whereby said external fastening means are provided with means for detection and/or measurement of relative displacement between said at least two external fastening means, whereby the bone is subjected to strain, and

whereby corresponding measurements and/or detections are made of the relative displacement in at least two dimensions and of the strain on the bone.

7. Method according to claim 6, characterized in that measurement and/or detection of the relative displacement may comprise measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement.

8. Method according to claim 6 or 7, characterized in that the external fastening means are part of external fixing means for supporting the bone.

9. Method according to claim 6, 7 or 8, characterized in that the bone is subject to strain by the patient and in that the strain is measured, detected and/or visualized.

10. Method according to one or more of claims 6 - 9, characterized in that the corresponding measurements and/or detections of the relative displacement and of the strain on the bone are correlated and/or recorded.

11. Apparatus for measuring the strength of a bone, in particular a bone having a healing osteotomy or a healing bone fracture, said apparatus comprising external fastening means for connection to the bone in at least two locations, said external fastening means being provided with means for detection and/or measurement of relative displacement by contactless measurement and/or detection means between said at least two external fastening means.

12. Apparatus according to claim 11, characterized in that the apparatus is provided with means for measurement and/or detection of induced strain on the bone.

13. Apparatus according to claim 11 or 12, characterized in that the apparatus is provided with means for correlating said measurements and/or detections of relative displacement of strain.

14. Apparatus according to one or more of claims 11 - 13, characterized in that the means for contactless measurement and/or detection of relative displacement between said at least two external fastening means facilitate measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement.

15. Apparatus according to one or more of claims 11 - 14, characterized in that the external fastening means are part of external fixing means for supporting the bone.

16. Apparatus according to one or more of claims 11 - 15, characterized in that the apparatus is provided with means for supporting one or both ends of a limb, for positioning one end of a limb and/or for transferring forces to/from the limb to/from measuring means.

17. Apparatus according to one or more of claims 11 - 16, characterized in that the apparatus comprises means for indicating, visualizing and/or recording the measured and/or detected strain.

18. Apparatus according to one or more of claims 11 - 17, characterized in that the apparatus comprises means for indicating, visualizing and/or recording the measured and/or detected relative displacement.

19. Apparatus for measuring the strength of a bone, in particular a bone having a healing osteotomy or a healing bone fracture, said apparatus comprising external fastening means for connection to the bone in at least two locations, said external fastening means being provided with means for detection and/or measurement of relative displacement in at least two dimensions between said at least two external

fastening means, said apparatus being provided with means for measurement and/or detection of induced strain on the bone.

20. Apparatus according to claim 19, characterized in that the apparatus is provided with means for correlating said measurements and/or detections of relative displacement and strain.

21. Apparatus according to claim 19 or 20, characterized in that the means for detection and/or measurement of relative displacement in at least two dimensions between said at least two external fastening means facilitate measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement.

22. Apparatus according to claim 19, 20 or 21, characterized in that the external fastening means are part of external fixing means for supporting the bone.

23. Apparatus according to one or more of claims 19 - 22, characterized in that the apparatus is provided with means for supporting one or both ends of a limb, for positioning one end of a limb and/or for transferring forces to/from the limb to/from measuring means.

24. Apparatus according to one or more of claims 19 - 23, characterized in that the apparatus comprises means for indicating, visualizing and/or recording the measured and/or detected strain.

25. Apparatus according to one or more of claims 19 - 24, characterized in that the apparatus comprises means for indicating, visualizing and/or recording the measured and/or detected relative displacement.

26. External fixator for supporting a bone, e.g. a bone in a limb of an animal or a human being, said fixator comprising means for fastening onto the bone in at least two locations and connecting means for providing a preferably adjustable connection

between said fastening means, wherein said connection means are replaceable and wherein measurement and/or detection means for detection and/or measurement of relative displacement between said at least two external fastening means are attachable onto said at least two external fastening means.

27. External fixator according to claim 26, c h a r a c t e r i z e d i n t h a t said measurement and/or detection means for detection and/or measurement of relative displacement between said at least two external fastening means are contactless.

28. External fixator according to claim 26 or 27, c h a r a c t e r i z e d i n t h a t said measurement and/or detection means for detection and/or measurement of relative displacement between said at least two external fastening means are configured for detection and/or measurement of relative displacement in at least two dimensions.

29. External fixator according to one or more of claims 26 - 28, c h a r a c t e r i z e d i n t h a t said at least two external fastening means may each comprise or be connected to a structural member which surrounds the body part containing the bone at least partly, and in that said preferably adjustable connection between said fastening means may be connected to said structural members.

30. External fixator according to claim 29, c h a r a c t e r i z e d i n t h a t said structural members may comprise separate and/or relatively movable parts which may be joined and/or adjusted in order to surround a limb at least partly.

31. External fixator according to one or more of claims 26 - 30, c h a r a c t e r i z e d i n t h a t the connection means comprise one, two, three, four or more connecting rods, which may preferably be adjustably placed between said at least two fastening means.

32. External fixator according to one or more of claims 26 - 31, c h a r a c t e r i z e d i n t h a t the measurement and/or detection means for detection and/or measurement of relative displacement between said at least two external fastening means are

attachable to said structural members forming part of or being connected to said at least two external fastening means.

33. External fixator according to one or more of claims 26 - 32, characterized in that the measurement and/or detection means for detection and/or measurement of relative displacement may be connected to the at least two external fastening means and/or said corresponding structural members by means which also serve as fixing means for said preferably adjustable connection between said fastening means.

34. External fixator according to one or more of claims 26 - 33, characterized in that the measurement and/or detection means for detection and/or measurement of relative displacement may comprise electrical, magnetic or electromagnetic measurement and/or detection means.

35. External fixator according to claim 34, characterized in that the measurement and/or detection means for detection and/or measurement of relative displacement comprises optical measurement and/or detection means.

36. External fixator according to one or more of claims 26 - 35, characterized in that the contactless measurement and/or detection means for detection and/or measurement of relative displacement comprise one or more measurement and/or detection means.

37. External fixator according to claim 36, characterized in that the measurement and/or detection means for detection and/or measurement of relative displacement in at least two dimensions comprise two or more measurement and/or detection means placed at a circumferential distance, e.g. in relation to an axis of the bone.

Abstract:

Method and apparatus for measuring the strength of a bone, in particular a bone healing after a fracture or an osteotomy, whereby external fastening means are attached onto the bone in at least two locations. The external fastening means are provided with means for detection and/or measurement of relative displacement between said at least two external fastening means, the bone is subjected to strain, and corresponding measurements and/or detections are made of the relative displacement by contactless and/or two-dimensional measurement and/or detection means.

Hereby, measurements are made which will provide a more accurate assessment of the strength and/or stiffness of a bone. The invention also relates to an external fixator facilitating a method and an apparatus according to the invention.

(Fig. 3)

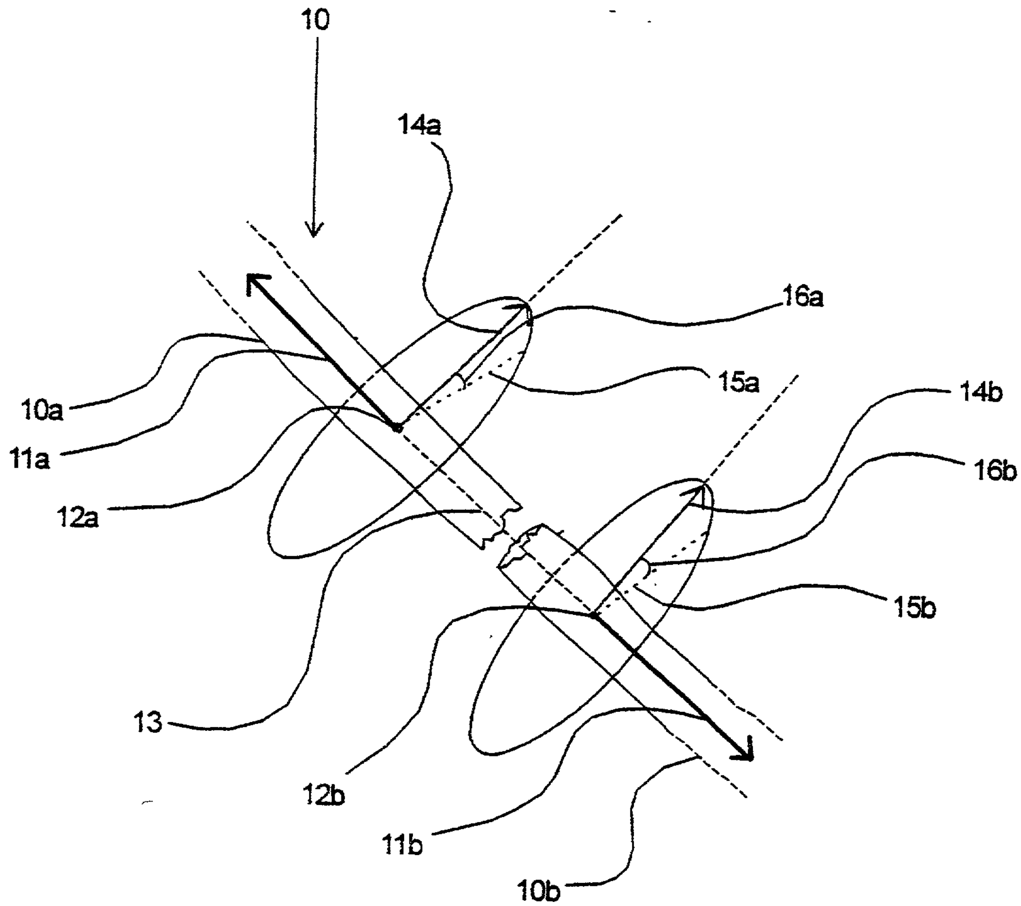

Fig. 1

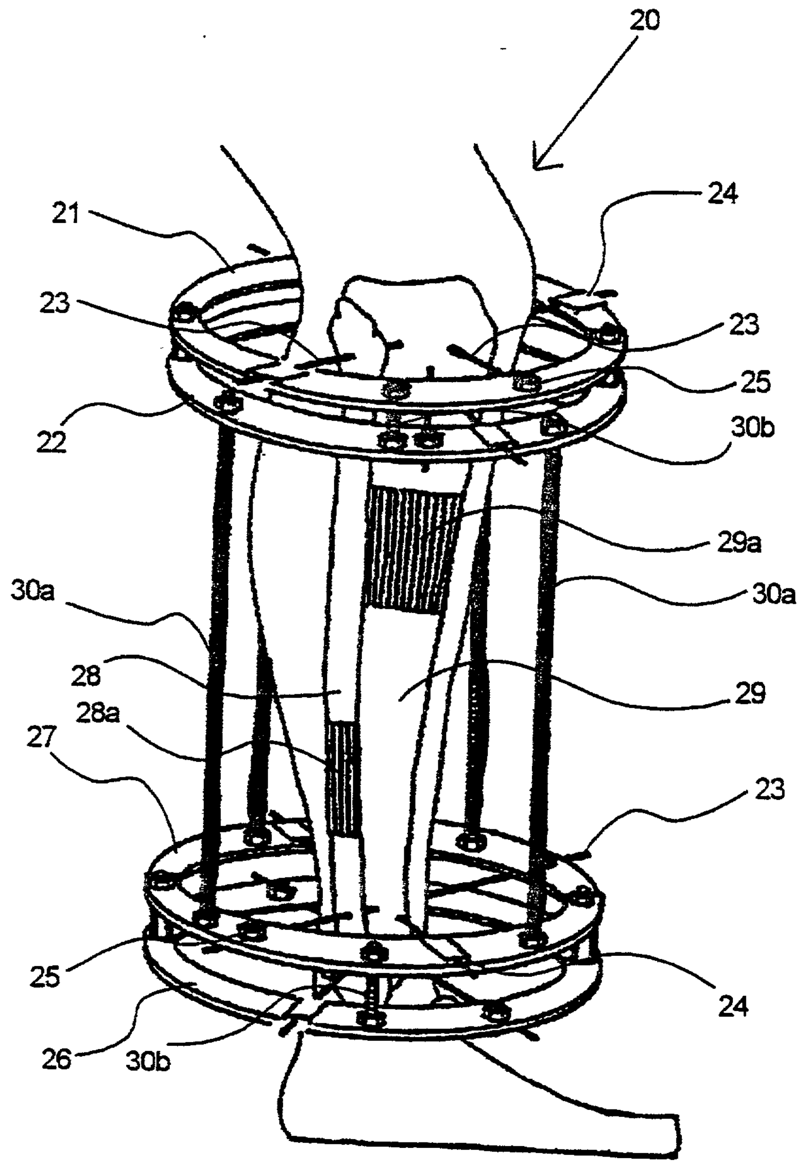

Fig. 2

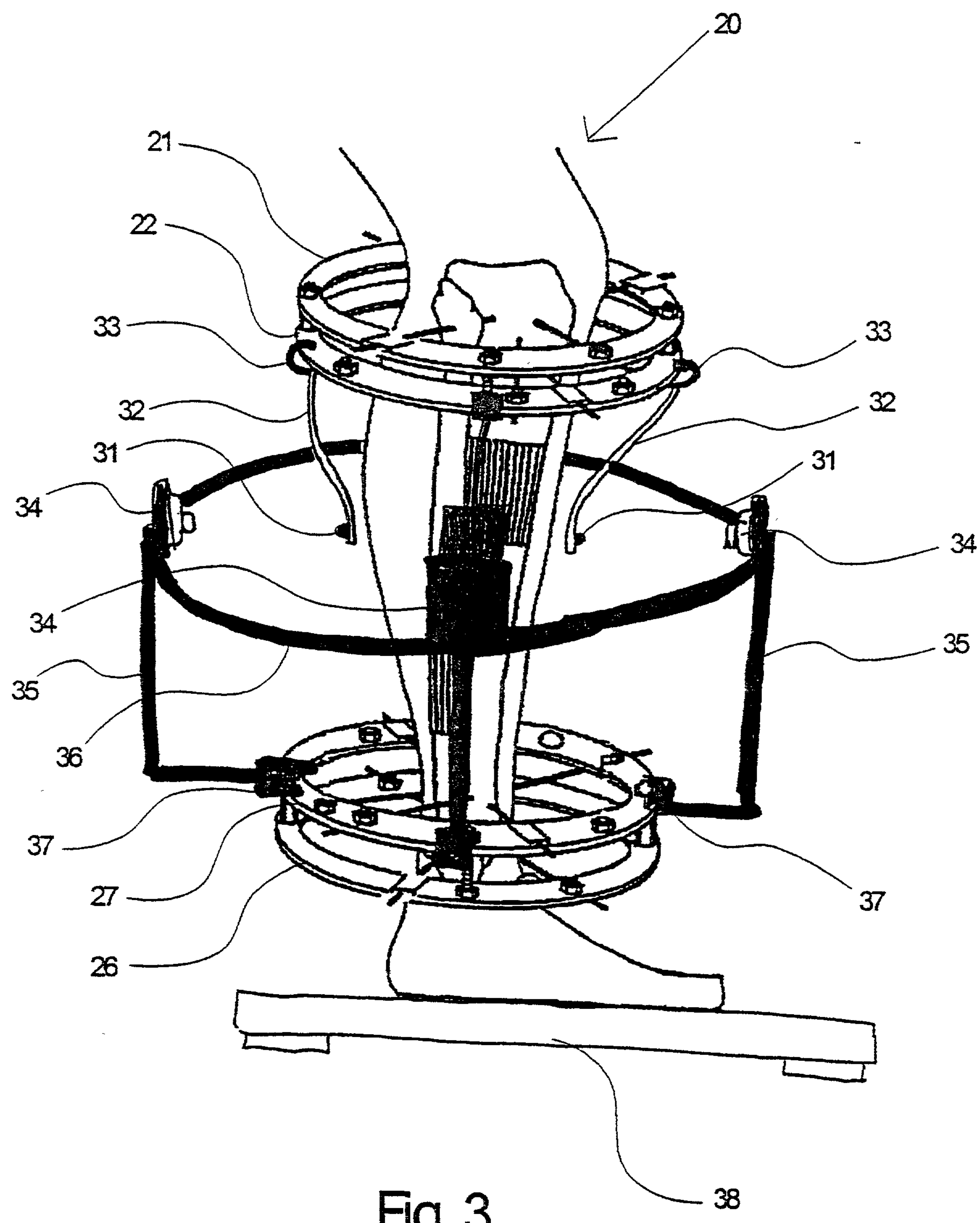

Fig. 3

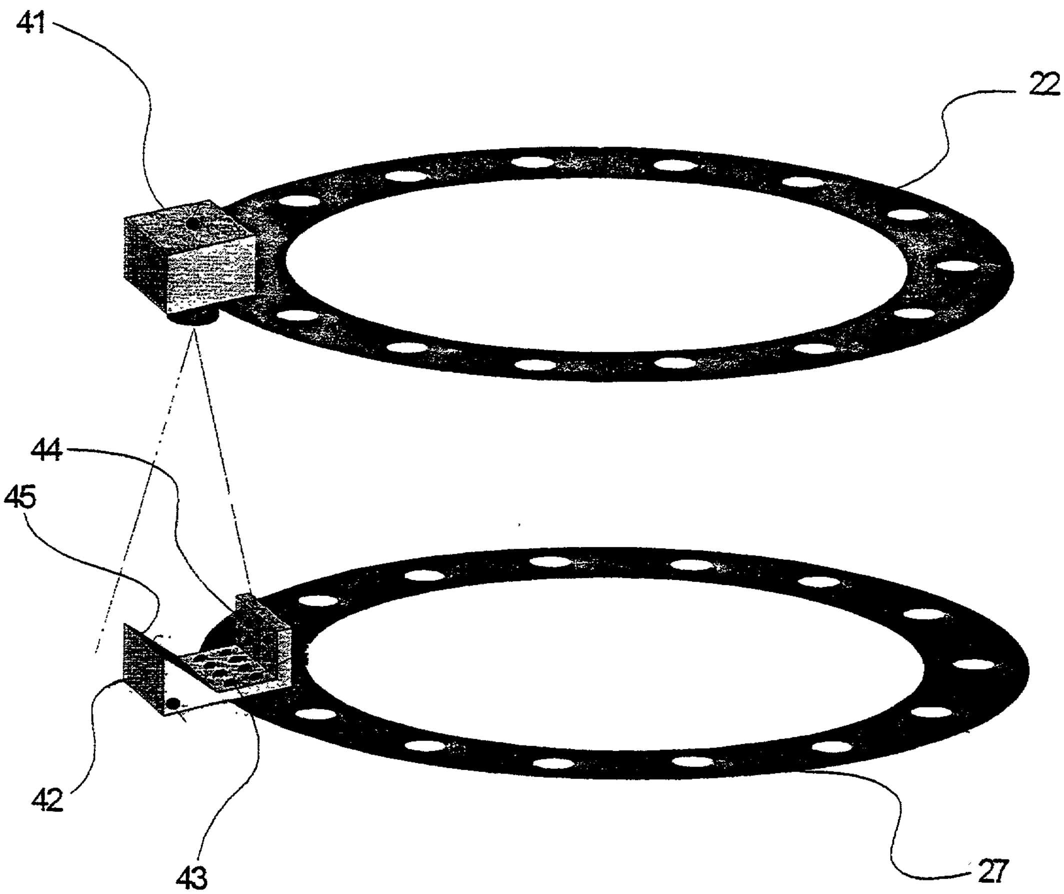

Fig. 4

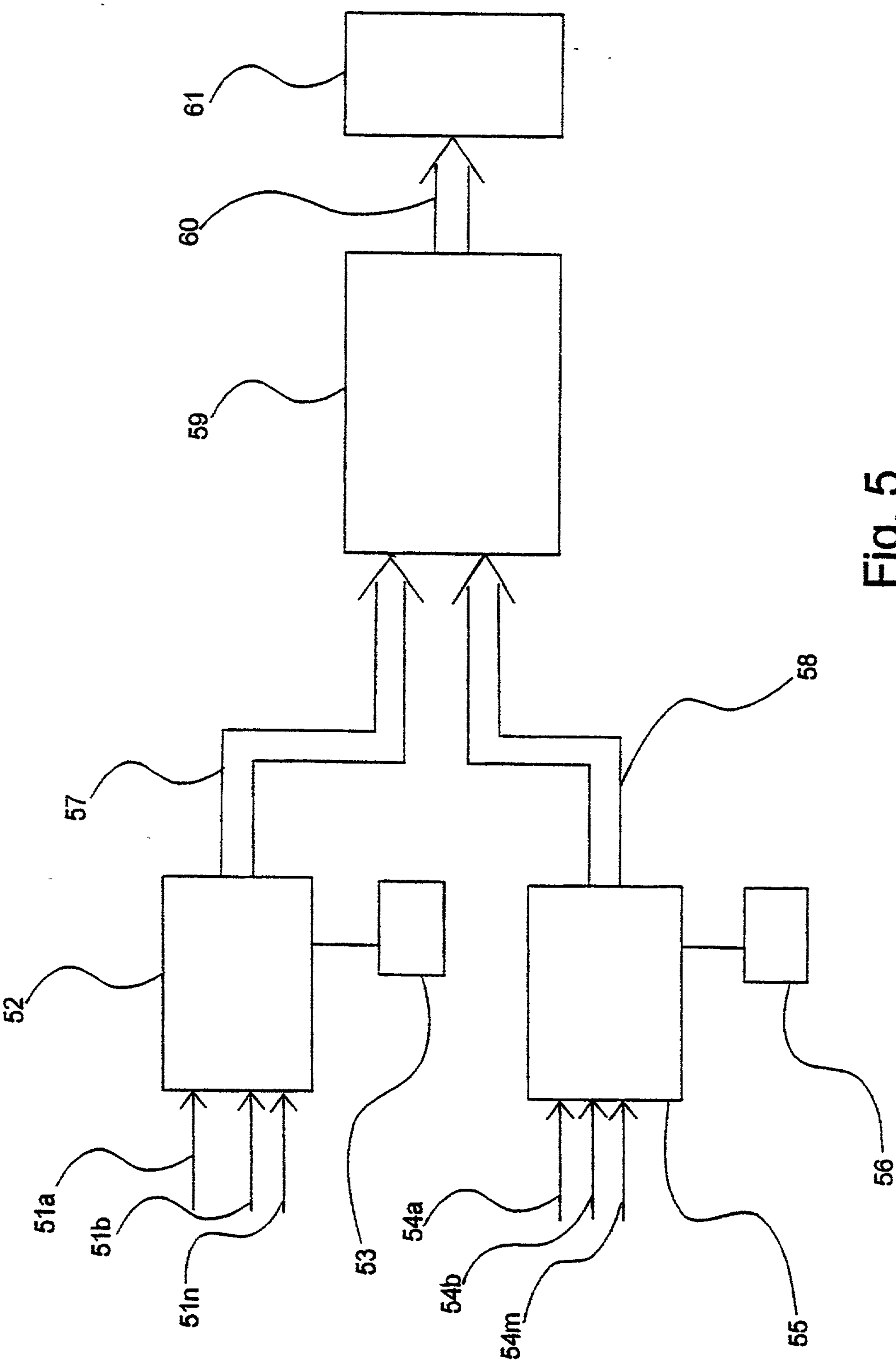

Fig. 5

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my/our name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled <u>METHOD OF MEASURING BONE STRENGTH, APPARATUS FOR MEASURING BONE STRENGTH AND FIXATION DEVICE</u> the specification of which

(check one)

_X_ is attached hereto.

____ was filed on ____________________ as

Application Serial No. __________________

and was amended on __________________

(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, 1.56(a).

I hereby claim foreign priority benefits under title 35, United States Code 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s).

(Number)	(Country)	(Day/Month/Year Filed)	Priority Claimed
PA 1999 01374	Denmark	28 September 1999	Yes
			Yes No

(Number)	(Country)	(Day/Month/Year Filed)

I hereby claim the benefit under Title 35, United States Code, 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

PCT/DK00/00529	27 September 2000	Pending
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

PROVISIONAL APPLICATION NUMBER	FILING DATE

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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